IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ICEUTICA PTY LTD., et al., : No. 14-1515-SLR-SRF
Plaintiffs, :
v. :
LUPIN LIMITED, et al., :
Defendants. :

Monday, June 15, 2015
10:00 a.m.

Discovery Review Hearing
Courtroom of Judge Sherry R. Fallon

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE Sherry R. Fallon,
United States District Court Magistrate

APPEARANCES:

FISH & RICHARDSON, P.C.
BY: ELIZABETH FLANAGAN, ESQ.
BY: CHAD SHEAR, ESQ.

On behalf of Plaintiffs

APPEARANCES CONTINUED:

PHILLIPS, GOLDMAN & SPENCE, P.A.
BY: DAVID BILSON, ESQ.

-and-

KNOBBE MARTENS OLSEN & BEAR LLP
BY: CHRISTY LEA, ESQ.
BY: WILLIAM ZIMMERMAN, ESQ.

On behalf of Defendants

ALSO PRESENT:

Martha Manning, Moji James and Stuart Moran,
iCeutica Pty, Ltd. and Iroko representatives

Mini Bhatt, Lupin Limited representative

THE COURT: Good morning, everyone. Please be seated. Let's start with the introductions for the Plaintiff iCeutica and Iroko.

MS. FLANAGAN: Good morning, Your Honor. Elizabeth Flanagan from Fish & Richardson on behalf of the Plaintiffs iCeutica and Iroko. With me today is my colleague Chad Shear.

MR. SHEAR: Good afternoon, Your Honor.

MS. FLANAGAN: And I have the pleasure to introduce several of our clients. We have Martha Manning who is general counsel for iCeutica. We have Moji James who is general counsel for Iroko Pharmaceuticals, and we have Stuart Maron who is assistant general counsel for Iroko Pharmaceuticals.

THE COURT: Thank you. And for the Defendants Lupin?

MR. BILSON: Good morning, Your Honor. David Bilson from Phillips, Goldman & Spence for Defendants Lupin. With me today at counsel table from Knobbe Martens is Christie

Lea and also Bill Zimmerman. In the courtroom with us is Mini Bhatt from Lupin Pharmaceuticals.

THE COURT: Good morning. All right. This was the time that I had scheduled for a discovery review conference. And for those of you and our corporate representatives here who have not previously attended a discovery review conference, it's simply an opportunity for me to touch base with the parties and with counsel to see how in general the fact discovery process is progressing, to address any discovery issues that may be percolating, and in this case we do have some discovery issues relating to the protective order which I will be addressing as we go along today, but also to make sure that the discovery in this ANDA case is proportional and that it's being exchanged in good faith and the parties are on target to meet the deadlines in the scheduling order.

The intent is that I will work with both sides in making sure that discovery progresses in an appropriate fashion so it's not

to derail the case from meeting the deadlines in the scheduling order. That's kind of the overarching intent. So with that, do the parties have any -- I'm not sure the order, if you've discussed in advance of this hearing the order of what you want to address the discovery review or do you want to address the discovery issues related to the protective order first.

Let me hear first from Plaintiffs on that.

MR. SHEAR: Your Honor, Chad Shear. We can handle those in any series that is convenient with you. On the discovery review aspect, I can simply say the Defendant has produced their core technical documents. We have produced infringement contentions. I don't think any of the parties have any concern with those two issues. So from our perspective the only issue remaining to be discussed is the protective order Your Honor mentioned.

THE COURT: Okay. Let me hear from the Defendants as well.

MS. LEA: Sure. And you will have to excuse me, Your Honor. I have a little bit

of a cold. So the Defendants do see it a little bit differently. We are concerned that we are off to the wrong foot on discovery. We have a couple of issues. We did serve 10 interrogatories on Plaintiffs. None of which were substantively answered.

For five of the interrogatories they relied on Rule 33(d), even though the interrogatories were at a minimal to a discovery answer. For example, Interrogatory 10 asked them to explain the basis for their standing. We do have two different parties here as licensees. Again, they just relied on Rule 33(d) With no documents produced, and of course, no actual reference to any documents.

THE COURT: All right. Well, let me just stop you there, Ms. Lea. Why don't we proceed this way: Let me hear first from the Plaintiffs. I will hear a little bit of background of the litigation. We can address the document discovery that's been exchanged, any pending interrogatories, Requests For Admissions, specific document requests that are pending and how that's proceeding here.

I will hear from Defendants on those points as well. Then we will take each issue that cropped up with regard to getting a protective order in place.

MS. LEA: Okay. And we do have one more issue, Your Honor, if I may.

THE COURT: Go ahead.

MS. LEA: The inventors on the patents are Australian. They are in Australia and we have asked Plaintiffs repeatedly to tell us whether they are going to bring them to the United States or whether they will voluntarily sit for deposition in Australa or whether we will have to resort to The Hague, and we have not gotten a definitive answer.

I was told on the phone that I would not have to resort to The Hague and they may voluntarily sit for deposition in Australia. But they have not been willing to tell me whether they have control over the inventors or they can either force them to come to the United States or whether they will voluntarily come to the United States. And this is something we have to work out quickly so that

if we need to resort to The Hague, we will need to get started.

THE COURT: Very well. Plaintiffs, Mr. Shear?

MR. SHEAR: Your Honor, on the discovery disputes we can handle that if you would like. I understood from your order that those issues wouldn't be raised this morning, but we are perfectly prepared and willing to discuss them if you'd like us to.

THE COURT: I will tell counsel that the only discovery disputes I'm going to hear and make rulings on today are the issues in the protective order concerning whether or not Lupin's corporate legal representative in India can have access to certain confidential designated documents and the patent prosecution bar. Those are the two issues I will address today.

Any further issues with regard to discovery, what I'd like to hear today is just the background of the case, what is prompting or behind these other discovery disputes that may be percolating and the parties' view on how we

should go about addressing them. I can set another discovery conference, whether in person or by teleconference at a future date. But if we're going to do that, I would like to hear from both sides before I give the parties any further indication of how that should proceed.

MR. SHEAR: Sure. Let me begin with a small background or brief background of the case. So Iroko and iCeutica developed and ultimately marketed a product called Zorvolex which is a pain medication used predominantly for immediate relief once pain onset has occurred. It could be post-surgical or a whole variety of situations.

Lupin is a generic drug company that has filed an abbreviated new drug application seeking permission for all intents and purposes to market a generic version of our product. So unlike typical patent litigation in a Hatch-Waxman case, the roles are very much reversed, wherein the Defendant is prepared months and months in advance for the litigation. Whereas frankly on the Plaintiff's side, it comes as a surprise as it did in this

case.

So once we received the Paragraph IV letter, we did our initial due diligence on that and filed suit here in Delaware and the case has been progressing since. The parties have each served initial discovery, responded to initial discovery and are working through the various issues associated with document production, document discovery, negotiation of search terms, the myriad of things that happen at the beginning of a lawsuit.

Now, on the specific issues that counsel has raised, perhaps I can go at them in reverse order.

THE COURT: Okay.

MR. SHEAR: Maybe that's easiest. The last thing I believe she mentioned was location of the depositions for the inventors. There are five inventors on the patents. One of them is located here in the U.S., and obviously the location for his deposition will be a nonevent. He's located in Philadelphia and that will be currently easy and he's a current employee of the parties.

The other four is a different story. None of them are employees. They're all third parties. Three of the four we are in contact with, but one inventor we've been unable to locate. So three of the four we are figuring out, A, whether The Hague process is necessary or, B, where the depositions will be taking place. As to The Hague, it's my understanding The Hague won't be necessary. They will agree and have agreed to voluntarily sit for a deposition.

THE COURT: But where have they agreed to voluntarily sit for --

MR. SHEAR: Well, that's part of the problem.

THE COURT: Without giving any type of preview on the ruling one way or the other, it's typically been observed in this District Court that if you are calling a witness to trial in Delaware, you should conveniently produce them for deposition if they are coming to trial. Again, I'm not making any ruling. I take these things on a case-by-case basis with full understanding of the circumstances, and I

think this is the type of issue that will not lend itself to a ruling today.

This is something I want to see some papers on, have some argument on before making a decision but I will give you the practice as you probably are familiar with as well just as a guidepost to figure this out. If we are going to keep on the scheduling order, those decisions can't be left lingering. You have a five-day bench trial in about a year-and-a-half or so, November 2016. And those decisions are going to need to be made, particularly if it involves witnesses coming to trial.

MR. SHEAR: Absolutely. And I can't stand here today and tell you who we will call or won't call at trial.

THE COURT: You said three out of four you have contact with even if they are no longer current employees of the Plaintiffs. What is the status with the fourth?

MR. SHEAR: We are unable to locate him.

THE COURT: Okay. All right.

MR. SHEAR: So for the three that we have been in contact with, as I said, they will voluntarily sit for a deposition. We have no contractual ability to force these people to the U.S. They are former employees, not current employees, and we don't have any contracts that I'm aware of that will enable us to force them to come here.

It seems to me that there are a variety of ways to ameliorate the situation, whether that's scheduling all of the depositions back to back in the same time frame if we have to go to Australia, whether that's doing the depositions by video. It seems to me there are ways we can ameliorate the situation that will address everyone's concerns.

THE COURT: The discussion of those alternate means of taking discovery, how far into the discussions have you got, if any, with the other side with the Defendants?

MR. SHEAR: We haven't had a chance to discuss this yet. We are still talking to the inventors to try to get a sense of whether or not they will come to the U.S. I

know for one of the inventors, specifically he just started a new job in Australia and it will be incredibly difficult for him to come here for a deposition. I don't have any information on the other two.

THE COURT: Unless you had more to say regarding the depositions, do you want to address the other issue raised with regard to outstanding interrogatories, 10 interrogatories and Defendants' preview that there may be a discovery issue with regard to the sufficiency of responses.

MR. SHEAR: Sure. In the first instance, I will be surprised if there is a dispute. Obviously, if in the end our responses are insufficient, then it's going to be us that's hampered at trial. Now, with that being said, the way in which this came down, we received a one-paragraph email generally stating they had concerns with discovery, which is not typical I think of how the practice operates.

Usually each side exchanges lengthy letters and the parties get on the phone and work things out. We had a lengthy meet-and-

confer based on the one-paragraph email in which every single Request For Production was gone through on an itemized basis, and we are in the process right now of addressing the concerns that were raised at that meet-and-confer and we promised to them a response in writing, and they will have that letter this week.

So I think the dispute right now is premature. But if there's any specific issues that need to be addressed, we are happy to address them.

THE COURT: All right. Anything further with regard to how fact discovery is progressing in general? You are beyond production file history, Defendant's ANDA, the initial infringement contentions.

MR. SHEAR: We are. And all of those dates have been complied with.

THE COURT: So no further issues other than getting to the protective order issue? No further issues from Plaintiff this second?

MR. SHEAR: Not as far as I would say. I guess in general we are still in the

infancy of discovery and the parties are working on search terms for those types of things, so it would be unusual to expect in my experience a precise response to interrogatories where Rule 33(d) would be permissible and appropriate to be citing documents immediately.

We have already made one document production and we will make further document productions. We are working on supplemental interrogatories. But all of those things will generally flow in the normal course of discovery. The document production is set to be over in almost four months so we are progressing.

THE COURT: Okay. Very well. Let me hear from Lupin with regard to the discovery and issues that the Court may have to address in the future.

MS. LEA: Sure. Your Honor, first of all, I will take his last statement. We disagree that Rule 33(d) is appropriate, and we explained the basis for standing. I'm sure there are agreements involved, but just to point to documents or even the specific agreements do

not explain their theory of standing which is what we ask for.

On the inventors, Your Honor, you're hearing what we've heard. But we haven't -- it's just a matter of when will they tell us. Can we have a date of when we're going to know about whether the inventors are coming to the United States, something in writing, if they are or even if they are not, can they voluntarily sit in Australia, so that we are not sitting and wasting our time and not applying under The Hague.

THE COURT: Well, it sounds like you need to have a conversation with Plaintiffs on those points. First, you're aware of my comments and concerns down the line of who is ultimately going to be here to testify at trial, how do you get discovery from those individuals. I think these are all issues that need to be addressed.

Your first efforts at creating a timeline or a date certain that you would like should occur first with your opposing counsel on those points before the Court needs to address

that. I would hope that these would be issues that counsel can work out, at least as far as taking the depositions and scheduling those depositions and what's going to happen with them.

MS. LEA: Just so Your Honor knows, we have had multiple phone calls and multiple emails on the inventors as well as the interrogatory responses, we have had a very lengthy meet-and-confer about the interrogatory responses and the document production. Many of the document production requests, they simply answered they are not going to produce documents.

And in the meet-and-confer, they said, well, it will probably be covered by the search terms. We finally do have their search terms and we are reviewing them. It was a little bit shocking to receive from them answers to many of the document requests that they simply would not produce documents.

THE COURT: It's my understanding from what Mr. Shear just represented that you will receive a response to the deficiency

notification that you sent to them this week, so perhaps what you can do is wait to get that response. We can set a date on the calendar if counsel wants me to do that.

I'm willing to set a date on the calendar to address both issues, both the deposition issues and the sufficiency of responses, but I'm not likely to be able to accommodate that date in July. So if you want to set something on the calendar for August, we can do it. And that's why I asked counsel to work it out as best you can in the interim.

MS. LEA: I would hope we can work it out, but I do think, Your Honor, the way things are going it would be helpful to have a date set on the calendar.

THE COURT: I'm not sure if my law clerk is able to provide a date. She will check the calendar and I will discuss that later in our hearing today. Why don't we move forward then if there are discovery issues, in the sense of giving me the overview of the discovery, how it's progressed to date. We can work into the protective order issues. I want to hear first

from Plaintiffs since they initiated the briefing on the protective order issue.

Mr. Shear, let's take one issue at a time. I have no preference as to how we start.

MR. SHEAR: I don't either, Your Honor. Perhaps we will start in the order the parties briefed the issues.

THE COURT: Very well.

MR. SHEAR: So as I started at the outset of the hearing noting that on the one hand we have iCeutica and Iroko, branded drug companies, who are in the business of making new products, and on the other hand we have a generic drug company making generic versions of those products.

We have a directly competitive issue. This is not a non-practicing entity case. This is not one of those situations where the parties are collaborating in a completely different field. This is a situation where the parties are in direct competition now and will be for the foreseeable future.

So my client has a direct, very

immediate concern about generally producing all of its confidential highly proprietary business documents over to the other side without some measure of protection. Now, the parties universally agree that a protective order is appropriate here and the parties universally agree that inhouse counsel should have access under the protective order.

Obviously, where the dispute is, is whether someone who is not an attorney should have access to those same materials, and that's where we drew the line.

THE COURT: Well, your position would not be to oppose access by inhouse counsel even if that inhouse counsel was located overseas or in India if that person had an "inhouse designation," correct?

MR. SHEAR: Well, first, that is a licensed attorney and I think that presents a totally different situation and one that we think would be in a different strategic footing.

THE COURT: How is that different from a corporate representative who is bound and subject to the jurisdiction of this Court in the

event sanctions needed to be imposed as well as the fact that the party itself is here on subject to jurisdiction and potential sanctions from the Court if certain confidential information is misused in violation of the protective order?

I need to see what the nexus is, why inhouse is permissible, but someone who perhaps functions, so to speak, as inhouse counsel doesn't have that attorney license is any different?

MR. SHEAR: Sure. The difference is found in the essence of the licensure requirement that you just referenced. An attorney, whether that attorney is licensed here or somewhere else, is subject to an entire set of rules separate and apart from just submitting to the Court's jurisdiction of obligations of ethical conduct, obligations of duties to the Court, et cetera, et cetera.

An inhouse person who is not an attorney and just rather a business person isn't subject to those same standards. So in an effort to sort of ameliorate the situation and

put things on balance, we had proposed seven conditions that we thought would put this inhouse person under the same sort of duties of ethics and candor and all of those things that a licensed attorney would be.

And if you look at the seven things that are listed, No. 1 is they would have to agree to be bound by the Delaware Rules on professional conduct. We would like this person put into the same spot that inhouse counsel would find themselves. Now, all of this is complicated by the fact that this person is not in the U.S. That makes things much more difficult so we have added additional conditions that we have placed on in an effort to compromise and resolve this without having to go before Your Honor to do that.

But what we are trying to basically seek is some measure of protection for our clients' interest for our confidential information, the same measure of protection that they are going to enjoy by the fact that all of the people that we want on the protective order are licensed attorneys.

And I should note that it isn't uncommon for a business person or scientist to have access to materials under a protective order. But that's when you have a two-tier system, and there's a second tier where things, although still confidential but not of the same nature of the other materials, and in that situation those business people may have access to certain limited subset information. But that is not what Lupin seeks.

Lupin seeks to have this nonattorney have the same rights and access to one that inhouse counsel might have.

THE COURT: Do you have any reason to believe that this representative designated by Lupin is involved is any competitive decision-making?

MR. SHEAR: The answer is, Your Honor, that I'm not sure. The Declaration that they submitted in support of their position is sore of scant when it comes to the details. But what Ms. Naidu does say is that she communicates with other groups about those litigations, she communicates with management and other groups

generally and provide updates about the litigation to management. So obviously, she will be updating people that are certainly involved in competitive decisions. Whether she herself is involved in those decisions, I'm not sure because I don't fully appreciate the nature of what her business responsibilities are.

And that I think, Your Honor, dovetails back to why we want this to be an inhouse counsel position. We all recognize that there are certain inhouse counsel that may be involved with business people involved in competitive decision circumstances, but because of the licensure requirements, because of the ethical obligations they have as attorneys, they are limited and they know what they can and cannot share with the business people in their organization with whom they might share information or who may be making those competitive decisions.

THE COURT: Would you have a level of comfort if you believed that Ms. Naidu not being bound by those ethical obligations, what if -- again, what if the Court would subject her

to the jurisdiction of this Court, require Lupin's counsel to so inform Ms. Naidu of what the ethical obligations would be if she had an attorney license?

Would those protections -- it sounds to me that your concern is about the ethical obligations that inhouse counsel are bound by because of their license. If Ms. Naidu was advised of these obligations and bound to conduct herself as if she were licensed under these obligations, would that create any difference? Would you have any problem with her reviewing the documents?

MR. SHEAR: I guess there are two issues. The answer to the first question, Your Honor, that would start us down the road that something we can certainly agree to. That was one of the first conditions we proposed, that she would be bound by the professional rules of conduct, which I think is in essence what Your Honor just suggested, that perhaps coming through Lupin's counsel as opposed to her independent review of the Rules. Either way that she becomes aware, it's fine with us.

The second concern that we have is our document production and certainly a subset of very sensitive information leaving the country and being sent to India wholesale to be reviewed by Lupin's inhouse business person. So those two concerns -- because you began by asking the question at the outset would it be different if it was inhouse counsel and I responded by saying it might be, not the circumstances --

THE COURT: Well, is that a real concern? We just spent some time in the issue before me talking about going to Australia for depositions with inventors who are no longer employed by the company. Is that not going to be a concern about taking sensitive information out of the country for purposes of direct and/or cross-examination for those inventors?

Where do we draw the line as to carving out when information can leave the country or not?

MR. SHEAR: The key distinction, Your Honor, the circumstance you just referenced to, it would be our confidential information

taken to Australia to share with our employees. The situation we're concerned about is our confidential information given to a direct competitor overseas.

At the end, Your Honor, the concern and I think the heart of this is if a disclosure takes place, that is, a breach of the protective order, whether inadvertent or not, how it happens doesn't matter, we have almost no recourse in India to kind of sort of put the cow back in the barn, so to speak. And that's really what we're worried about at the end of the day.

We don't have any problem with Lupin's counsel or outside counsel advising their client and talking to their client about confidential information, keeping her fully apprised of what's happening in the lawsuit. And I have been down this road before with Lupin in other cases with the very same situation. We don't have any problem with all of that information.

What we are trying to avoid is our confidential information to wholesale shipped to

India and reviewed by someone in India, so that's why and how we crafted the seven things we were hoping to try and balance the situation.

THE COURT: All right. And guide me -- specifically as you see I have read the protective order and flagged it and --

MR. SHEAR: So the protective order as it stands in front of you right now, Your Honor, is where the parties ended up -- it's limited strictly to inhouse counsel. The seven provisions that I keep referencing --

THE COURT: I thought it was Paragraph 5.

MR. SHEAR: It's actually Exhibit B, Your Honor. They are laid out in the correspondence between the parties. This is what we sent to Lupin asking if you agree to these conditions, we will agree to let Ms. Naidu in the protective order. Your Honor, it's my understanding this whole issue that Lupin raised with those conditions was the advanced notification provision which is Item No. 5, that the documents will leave the U.S. without prior consent.

And let me explain, the concern that Lupin raised was the fact that would require them to share their work product with us, and I completely understand it and appreciate it. I don't think that's what that paragraph is aimed at. The way that this is operated and practiced when we used this before is this is really aimed at briefs and depositions and the kinds of things that are going to the Court, and then a request comes in and says, okay, I see you attached Exhibit C and D which is marked as confidential, and we sent those. And nine times out of ten, it's not a problem depending on what they are. Usually, it's not an issue. In fact, in the last case I dealt with this, I can't think of a single instance where we said to Lupin that they weren't allowed to share the materials under that protective order under these conditions.

THE COURT: Thank you. Let me hear from Lupin.

MS. LEA: Well, Your Honor, counsel is right, the standard is the same whether it's an inhouse counsel or a nonattorney

employee, and the standard is whether they are involved in competitive decision-making. Here the Plaintiff has the burden to show that a protective order should be entered prohibiting information to share with Ms. Naidu, and they have not met that burden. They have not shown any evidence that she is involved in competitive decision-making.

She has submitted a Declaration explaining her tasks. None of which involve competitive decision-making. And certainly, having regular contact with other people, other employees in the company, even executives who do competitive decision-making is not enough to say that the attorney or the nonattorney is involved in competitive decision-making. If that were true, then all of the inhouse counsel would be involved in competitive decision-making. And the agreed-upon protective order actually says that, no, none of the inhouse or none of the representatives can be involved in competitive decision-making.

And, Your Honor, I do want to address that there are actual adequate safeguards

already in the protective order. During the action and 10 months after, none of the inhouse counsel or the representatives can participate in prosecuting patent claims relating to Zorvolex or the generic or even formulations involving Diclofenac acid. They cannot participate in submissions to the FDA or the U.S. Pharmacopeia and they cannot participate in business decision-making with respect to Zorvolex or generic Diclofenac. They're all required to institute a written acknowlegement and will submit to the personal jurisdiction of the Court.

And, Your Honor, we know that Judge Robinson has stated on the record that it is this Court's practice to allow at least one employee from the company to have access to confidential information, and that is in the Autozone case, and I do have a copy of that transcript if Your Honor would like it. And the simple fact of the matter is that Lupin Limited does not have an IP inhouse counsel. That job is of Ms. Naidu. I speak with her on a daily basis or communicate with her on a daily basis,

either by email or by phone.

She reviews every single filing that is submitted to the Court. And if she did not have access to confidential information, it would impede her ability to manage outside counsel and for her ability to advise the executives on the litigation. We have a situation where already the Plaintiffs are overdesignating. They designated their entire interrogatory response which had no substantive information and no confidential information as highly confidential, so we are in a situation that we have to go back and ask them to redesignate.

They designated their entire infringement claim charts as highly confidential. And I said is this because of our information. And they said, no, we are citing to our own confidential information. So we had to wait for a redacted copy of the infringement claim charts before I could even send it to Lupin's representative Ms. Naidu.

THE COURT: Why don't we address some of the protections that might address both

parties' concerns. I think what I'm hearing is you want to be sure your representative can have access to the confidential information. Are you willing to have her informed by inhouse counsel as to what the professional rules of conduct ethically require that she observe as if she were inhouse counsel? Is that an issue?

I'm trying to get to what number of these seven conditions suggested by Plaintiffs would be just opposed by the Defendants. And I think maybe it just does involve really No. 5. Unless you tell me otherwise, I can't fathom a situation in which a Defendant would object to someone being bound by a professional code of conduct, someone being bound by ethics and someone submitting to jurisdiction to this Court of enforcement of those types of conditions.

So how do we work around Plaintiffs' concern about documents leaving the United States?

MS. LEA: So we do have no objection to Conditions 1 and 2. Three and four, those are contract terms, irreparable

harm, jointly and severally liable. And if we want to turn it into a contract, we all can agree to be bound by that contract. But Plaintiffs themselves said in Paragraph 21 which says this is not a contract. And then Condition 5, we see that as two issues with that, number one, it's unworkable. Ms. Naidu is in India so she's not going to be in our office to see the confidential information our office.

We also see it as infringing upon our work product and attorney-client communication, so to the extent every time we communicate a piece of confidential information to Ms. Naidu, we have to first disclose to Plaintiff that we intend to do so and get their permission to do so, and that goes for 5, 6 and 7.

THE COURT: How about, and maybe I should ask this to Mr. Shear. How about a situation where -- well, I'm not sure if it will work. If you're saying the Plaintiffs are overdesignating confidential materials, I was wondering rather than Lupin advising of every piece of information that leaves the United

States, Plaintiffs indicating which documents under which circumstances should not leave the United States rather than making a blanket prohibition and just having the Court address them if the parties can't agree?

MS. LEA: That might be more helpful. I'm still not sure how I see the difference here between Ms. Naidu as an IP manager than an attorney. That's not how the cases deal with this issue. It all comes down to whether the nonattorney representative is involved in competitive decision-making and she's not. She's managing the litigation and reporting on it.

And as a practical matter, of course we do not plan to ship all of their documents to India. I don't believe that any inhouse representative is sitting around reviewing documents. What we plan to do is send the infringement claimant charts they sent us where they cite to their confidential information. We plan to send that to Ms. Naidu so that she can advise us on the infringement contentions that are at issue in the case.

And in any briefing that might have a quote or something else from their confidential information, that's what we intend to share with Ms. Naidu. And I will say, Your Honor, we did cite to one protective order where Ms. Naidu has previously been granted attorney-level access and there hasn't been any issues in that case. I'm not sure what the Plaintiffs are referring to when they say they have dealt with Lupin on protective order issues. I'm not aware of those. They didn't disclose those during any kind of meet-and-confer.

But I have to come back to the point that IP management is not competitive decision-making. That is in the case law that we've cited, and they simply have not met the burden to question her role in the litigation, her ability to adhere to the protective order, and they haven't made a showing about any confidential information. Their product is public. We have already released our generic product.

I'm not sure what they're

concerned about, about their historical development documents or their historical development information. They haven't made any type of showing or even tried to.

THE COURT: Thank you. Anything further in rebuttal, Mr. Shear?

MR. SHEAR: Just briefly, Your Honor, a couple of quick points. Counsel noted all these other cases that talk about competitive decision-making, however, with the exception of maybe one that counsel cited, they are all talking about counsel, not business people. As to the overdesignation, there have been two things that have been designated so far.

One we designated highly confidential because it contains Lupin's highly confidential information as well as ours. The other one is an oversight which we've corrected. They brought it to our attention Friday night and we fixed the problem Sunday morning. So I don't think there's really much of an issue there.

And then lastly and sort of

importantly, the exact kind of thing that counsel just was talking about with respect to the types of materials they want to share with Ms. Naidu is exactly the kind of thing that I said at the outset, the kind of thing that we would be willing to agree to on a case-by-case basis, which is what Condition No. 5 is really aimed at.

I don't think at the end of the day that we will have a concern with Ms. Naidu reading our infringement contentions, validity contentions, the kinds of things she really needs to review to work with counsel. And notably, we don't have a problem with counsel talking about all of these things. So --

THE COURT: But isn't that an intrusion on counsel's ability to conduct the litigation if they basically have to check in with you, the opposing side, every time they want to have a communication with the client representative about a confidential document? Would you want them knowing every time you're having an inhouse conference with your inhouse people?

MR. SHEAR: Of course, we agree with that. But with respect, I don't think that's what we are trying to achieve. I don't think that we're trying to achieve a situation where Ms. Lea isn't free to discuss with her client anything she wants to discuss. She of course is. It's the providing of our materials outside of the U.S. that causes us concern, and it's just really that in a nutshell.

THE COURT: Anything further on this point?

MR. SHEAR: No, Your Honor. Do you want me to move to the IPR?

THE COURT: I tend to rule on these issues one at a time. So having heard the arguments of counsel and having reviewed the authorities that give some guidance on this point, a primary consideration and this is from the U.S. Steel Corp. case, a primary consideration whether to permit inhouse legal representatives to have access to opposing party's confidential information is whether that representative is involved in competitive decision-making, and that involves a degree into

the factual circumstances surrounding each individual counsel's activities, association, relationship with a party which must govern any concern for inadvertent or accidental disclosure.

And I can understand Plaintiffs' concerns that once inadvertent or accidental disclosure gets out of the box, so to speak, it's hard to stuff it back into that box or cower the horse back into the barn, to use counsel's analogy. I do understand the concerns about not having that occurrence happen. On the other hand, in terms of something this restrictive, the Plaintiff does really bear the burden of having these restrictions set in a protective order.

And I think the seven conditions that I've read in Exhibit B to the submission of Plaintiffs are overly restrictive in a sense in which they would impede Defense counsel's ability to litigate the case and go forward with their litigation strategy and have conversations with a corporate representative in a fashion and in a way that they would be meaningful to

preparing the defense.

So with that, I am going to allow Ms. Naidu to have access pursuant to the protective order. I will include the condition that she subject herself to this Court's jurisdiction, that she agree to all of the confidential obligations that she is required to adhere to if she is going to have access to that information.

I will also include, if not already included by the formal representations, that she will sign onto to protect confidential information, just to make it clear, that she is bound by Conditions 1 and 2 of the Plaintiffs' proposals in Exhibit B of that submission. And that is, that she agree to be bound by Delaware lawyers rules of professional conduct and that she agrees to submit to the jurisdiction of the Court's enforcement of the protective order.

So having said that, if there is a concern somewhere down the line during the course of the litigation that an inadvertent disclosure is more likely than not to happen because of the discovery exchanges or if there

is a particular document or collection of documents or collection of materials in discovery that Plaintiffs have particular concerns about leaving the country, the Court is certainly open to hearing any discrete and specific instances so that I can weigh in as necessary or as appropriate before the odds are stacked that make it more likely than not that an inadvertent or unexpected disclosure of information will occur.

But I think that we live in a global world. We have litigation of two parties that have connections outside of the United States, and there is a need on both sides to have information go out of the United States. But nonetheless, there are very distinct and specific concerns about keeping such information confidential. And I think and expect that the parties will see that as paramount, that information designated confidential stay confidential and that the risks are minimized to avoid any inadvertent disclosures whatsoever.

Like I said, if there are particular concerns that come up during the

course of the exchange of information between the parties, I will try to address those before there is an issue with the cat out of the bag, so to speak, and we will have to do something to address that situation which is more difficult than not getting it out of the bag at all.

And with regard to the rulings that I'm making today on these discovery issues, it is my practice and I think counsel here are all familiar with it, but I will repeat it just in case, this transcript will serve as my ruling. I will not be issuing a written order. Since we are dealing with a draft protective order, once you have my rulings today, I would ask the parties to meet and confer and that one side or the other take the lead in getting a revised protective order to my chambers so that I can enter it on the docket that incorporates a protective order that incorporates the rulings that I'm making here today.

With that, we can proceed to the next issue which is the issue relating to the prosecution bar, and specifically, as it relates to post-grant activities.

MR. SHEAR: Thank you, Your Honor. I think I'm first on that one as well.

THE COURT: Okay.

MR. SHEAR: So again, this is a fairly focused issue. The parties obviously agree to a protective order. They agree that a prosecution bar is appropriate. Where we disagree is the scope of that prosecution bar, and specifically, whether or not someone who has access to materials under the protective order should also be allowed to participate in post-grant.

THE COURT: Let me give you a little guidance here because I have thought a lot about this issue in advance of our hearing today, and I have read both Kenexa and Versata, and admittedly there's contention between the two. And these issues have to be addressed fact specific on a case-by-case basis.

So tell me what about the prosecution bar to put it in the Kenexa camp or Versata camp, where are we from Plaintiffs' perspective on the conflict of the two decisions?

MR. SHEAR: I think they are actually more in line than what we may think. So on balance, the focus of this issue is on the one hand we want to be in a position where we wouldn't be forced to potentially inadvertently take inconsistent positions in both places which is what Versata is addressing and to a lesser extent but also what Kenexa is addressing. The balance against Lupin's concern is that we cannot use any of their confidential information in front of the Patent Office.

Now, the post-grant procedure as it exists today, it wasn't always this way, but as it exists today you can't broaden the claims. It's incredibly difficult to amend them, so the likelihood that an inadvertent use of confidential information is very, very small. But I think that if you look at the Versata decision and you want to try to square Versata with Kenexa, Versata is aimed at balance that I just talked about between one side's desire not to take inconsistent positions and the other side's desire that their information not be used.

And in that case because of the balance issue, specifically the source code, was a very easy line to draw. Because on a typical litigation team, the source code is so dense and not everyone uses or even looks at the source code. It's too much, so it was easy to identify a couple of attorneys. They could operate both points.

THE COURT: How do you address on that point Lupin's argument that Lupin's formulation is analogous to source code material?

MR. SHEAR: Sure, and I think it's a fair statement, but I think the key difference is that we're trying to meet and give them the same protection Versata gave the Defendant in that case by saying that the litigation counsel will play no part whatsoever in amending or drafting of any claims. So to the extent the claims are going to change at all, litigation counsel will not play any part in that.

Instead, while we might help patent prosec -- to the extent by the way, this is all hypothetical. There hasn't been an IPR

filed --

THE COURT: I was going to ask that question, but --

MR. SHEAR: I should have led with that.

THE COURT: -- thank you.

MR. SHEAR: But to the extent that an IPR was ever instituted, what litigation counsel might discuss with prosecution counsel -- I'm not even sure it's fair to call them prosecution counsel based on the way recent decisions have described it as an adjudicatory proceeding as opposed to true prosecution, but to the extent that we would have those conversations, we might talk about positions to take vis-à-vis the publicly available prior art, those kinds of things.

But what we wouldn't do is be involved in any way in the changing of claim scope. The claims from our perspective will be as they are today, and that will give them the same measure of protection of Versata, because that's really what Versata was aimed at. They didn't want litigators changing the scope of the

claims. And we would agree not to change the scope of the claims after having access to their confidential information.

THE COURT: All right. Let me hear from Lupin.

MS. LEA: So the prosecution bar in Versata was not limited to claim amendments. It was a complete prosecution bar for any type of post-grant proceeding including re-examination and IPR. And the way I would distinguish Versata and Kenexa, Your Honor, is the difference in time. There's somewhat of a trend in this District for the more complete prosecution bar, and that started occurring after the Federal Circuit issued its decision in May 2010, In re Deutsche.

There the Federal Circuit put the burden on the parties seeking the exemption. The burden is on the Plaintiff here to show that their representation before the Patent Office is not likely to implicate competitive decision-making. I think what he stood here and said what they want to be able to do is exactly that, competitive decision-making.

They want to be able to structure their validity argument in a way that will not harm their infringement argument in the District Court. And this is a situation, Your Honor, where the ANDA formulation for Lupin is different than the Zorvolex formulation that Plaintiffs have. If their prosecutors were to know that formula, that could affect their arguments in the Patent Office, even in post-grant proceedings.

THE COURT: I'm sorry. I'm looking at Versata. It says parties seeking to include a protective order, a provision affecting a prosecution bar has the burden of showing good cause for its inclusion. That's from the Deutsche Bank case. I'm sorry. I'm not following your argument on burden.

MS. LEA: Right. So the party seeking a prosecution bar has the burden to show good cause, but the parties here have an agreed-upon prosecution bar so that burden has been satisfied. Now, if a party wants an exemption, they want to carve some prosecution, like re-examination or IPR, then it's their

burden to show that exemption. And that's what In re Deutsche said.

Also, Inventor Holdings out of this District in 2014 says the same thing. In that case, this Court did not do a carve-out. They said, no, a prosecution bar is going to include re-exam and IPR just like in Versata. And, Your Honor, I did want to make one correction. There's somewhat of a misstatement in Plaintiffs' letter that we did not catch. And I would just like to point it out.

They cited to two sample protective orders from other districts that they say include a limited prosecution bar that carves out re-exam and IPR, and that's not correct. The Northern District of California order, that's Exhibit E. That one --

THE COURT: Hang on. Let me take a look at it. Okay.

MS. LEA: Exhibit E, Paragraph 8.

THE COURT: I have it.

MS. LEA: So we have a prosecution bar set forth in Paragraph 8. It includes a complete prosecution bar. And then it says, and

I'm at Line 9, to avoid any doubt prosecution as used in this paragraph does not include representing a party challenging a patent before a domestic or foreign agency, including but not limited to a reissue protest, ex parte re-examination or inter partes re-examination. So it's only the party that's challenging the patent that may participate.

THE COURT: Okay.

MS. LEA: Again, Your Honor, I come back to Versata and that our formulation as they admit is like the source code. It's the big secret here that their clients do not know. And that if their prosecutors were to know, could affect their prosecution including their post-grant strategy. And that is taken, Your Honor, from the Patent Case Management Judicial Guide.

And I will say since this lawsuit has started, they have had two patents issued that they have added to the lawsuit they are continuing to actively prosecute. They have four more applications they received a Notice of Allowance on.

THE COURT: All right. Mr. Shear?

MR. SHEAR: Just two brief points, Your Honor. First of all, yes, we have more patents coming out. That's prosecution. We are not talking about prosecution bars here.

THE COURT: Post-grant review.

MR. SHEAR: Correct. Now, counsel referenced the In re Deutsche Bank case. Specifically, I will read the quote from the case. The quote is, strategically amending or surrendering the claim scope during prosecution to constitute competitive decision-making. And that's exactly what we're saying we will not do here. We won't be involved in change of claim scope in any way, shape or form and that is written in the protective order as it stands.

So I disagree with counsel's characterization that this is about timing and scope. At the end of the day, it does come down to competitive decision-making as it affects the claim scope, and that is what we are saying we will not be involved in. Thank you.

THE COURT: All right. The parties have agreed to a prosecution bar in this

case. The issue is whether to include Plaintiffs' proposal which is set forth at various portions of the draft protective order. But to generalize, Plaintiffs' proposal includes a carve-out from the prosecution bar which would not preclude outside counsel from participating in post-grant review types of proceedings to challenge or defend the validity of any patent, but outside counsel may not participate in the drafting or amending patent claims in any such proceedings.

I've spent some time reviewing Judge Robinson's opinions, both in the Kenexa case and in the Versata case and recognized that these decisions have to be made on a case-by-case basis. There's no general blanket rule that can be applied other than the standards and putting in place protections which would, as Judge Robinson said in Kenexa, protections such that no party should use confidential information to obtain additional rights for itself, but they should be able to use it to divest each other of their respective rights.

And as she noted in the Kenexa case, the scope of claims cannot be enlarged by amendment in a re-examination because the re-examination involves only the patent and the prior art, Defendant's confidential information is basically irrelevant to the re-examination. I realize that in Versata that she reached a different conclusion and was more restrictive about a patent prosecution bar which prohibited any attorney, consultant, witness or other person who used highly confidential source code. It was source code in the Versata case at issue. She precluded those individuals from participating in any patent application, prosecution or any post-grant review proceeding for the particular technology field at issue in the patents-in-suit, and further prohibited them from consulting with the attorneys or experts participating in any such prosecution or post-grant proceeding.

In this instance, I'm going to allow the Plaintiffs to include the carve-out language that they have suggested. Having reviewed both decisions and considered the

arguments in this case and the fact that presently there are not any post-grant review proceedings taking place, not that that would alter the outcome in and of itself if there were, but I'm not convinced that in this instance the level of protection or concerns raised by Lupin rise to the level of those concerns in Versata with regard to use of source code in an inappropriate way that might implicate competitive decision-making.

So I'm going to, as I said, permit the language proposed in Plaintiffs' version of the protective order. There are several instances where that language was inserted. I'm not sure if I marked out all of them. Just for purposes of the record, the ones that I've flagged are at Page 7 and 8 and 10 and maybe elsewhere throughout the protective order, but those are the ones I've caught.

If there are any other locations where that language needs to be revised or incorporated in the protective order, then I will expect, again, that the parties will get together and one side or the other will send to

my chambers a revised protective order consistent with the rulings that I've made.

In the event that there are certain post-grant review proceedings initiated and there is a concern by the Defendants about access and use of confidential information in those proceedings, again, these rulings are without prejudice for the Defendants to bring to the attention of the Court anything preemptively that I can address before the cat is out of the bag, so to speak. I hate to use that analogy, but this is a safe way of putting it. And I will consider specific and discrete instances at that time and address them.

But viewing these things in general, I try to make decisions that afford the protections that the parties are seeking while not tying the hands of either side, retained counsel or inhouse counsel or the parties themselves from pursuing certain litigation strategy, developing litigation strategy and going forward using the materials that are produced in discovery in a manner consistent with their objective in the litigation.

So I try and balance all of those things in making these rulings so there is a sense of fairness and predictability, and also so the parties are aware that the Court share the concern and recognize the concerns about protecting confidential information but also protecting each party's rights to litigate as they feel is appropriate and consistent with the objectives of each party.

So having said that, as all of you know these are nondispositive rulings. So under Rule 72, should either side object to any of the rulings today, you can take it up with the District Judge. The District Judge in this case can consider timely objections and modify or set aside any part of the order that is clearly erroneous or contrary to law.

And again, this transcript will serve as the order. I will not be issuing a written order on either of these issues relative to the discovery order. We will set a time in August for hearing any additional discovery disputes along the lines of what we discussed today about depositions outside of the United States with the inventors or inside the United States with the inventors, and with regard to the sufficiency of responses to the Defendant's interrogatories that were served on the Plaintiff as well as any other issues that might crop up in the interim.

I have a date that I can give the parties, August 13th. And since I am the Criminal Duty Judge on that date, we would have to start the hearing after 3:30 p.m. So I guess tentatively I will set it for 3:30 on August 13th. And if, for example, my criminal calendar might run over that timeline, you might have to wait a bit. But usually, the criminal calendar is concluded by 3:00 so I'm comfortable with setting a time at 3:30.

I'm happy to do it in person if that's what the parties wish. If it's more convenient if the parties wish and agree to proceed by teleconference, we can do it by teleconference. I have no strong preference and I leave it to both sides on how to conduct that hearing, in person or by phone. So get back to my courtroom deputy Larisha Hicks on that, confirm the date and confirm when you want to start.

And then as the date approaches, submit your letter briefs as you did in this instance, limited to four pages, addressing the discovery issues. If there are going to be more than the two issues we've talked about, that is, the depositions and the sufficiency of Plaintiffs' responses to Defendants' interrogatories, please alert my courtroom deputy Larisha Hicks to that fact as well.

Going into these hearings, I like to know how much time to set aside for them, and also, I like to know in advance just how many submissions I'm going to be getting from each side. If both sides are responding to the other side, if the other party needs multiple submissions and if there is a way to streamline that, giving extra pages will reduce the number of submissions.

But for right now, just proceed with the briefing guidelines that are posted on the website. And if the necessity of the number of motions compel the parties to want to seek to

alter that or seek a different briefing schedule, then just make sure you make my chambers aware of that in plenty of time for me to take a look at it and give you some guidance on how you draft your submissions.

With that, is there anything further from the Plaintiffs today?

MR. SHEAR: No, Your Honor.

THE COURT: Anything further from the Defendants?

MS. LEA: No, Your Honor.

THE COURT: Thank you. And again, I thank the party representatives for being here. My purpose in asking for your attendance in the discovery review conferences is so that you are invested from the start in the discovery that your counsel is engaging in so that you're aware of how I view the process of fact discovery and so that you know that the Court is monitoring the case and seeing that the discovery is proceeding in accordance so that all of you get to your trial date on target and so that you all of you know that you have a forum to come back to if there are any disputes

or issues that will help facilitate the progress of the litigation.

I realize you've traveled a distance to be here and it's not a very long hearing and you may go back and think why does the Judge want me here, but I really do appreciate you being here and becoming invested in the process from the start. Thank you. We are adjourned.

MS. LEA: Thank you, Your Honor.

MR. SHEAR: Thank you, Your Honor.

(The proceedings concluded at 11:35 a.m.)

C E R T I F I C A T I O N

I, Taneha Carroll, Professional Court Reporter, certify that the foregoing is a true and accurate transcript of the foregoing proceeding.

I further certify that I am neither attorney nor counsel for, nor related to nor employed by any of the parties to the action in which this proceeding was taken; further, that I am not a relative or employee of any attorney or counsel employed in this case, nor am I financially interested in this action.

/s/Taneha Carroll
Taneha Carroll
Professional Reporter and Notary Public

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/s/taneha (63:16)

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accordance (61:21)
accurate (63:5)
achieve (40:3)(40:4)
acid (32:6)
acknowlegement (32:11)
action (32:2)(63:9)(63:13)
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activities (41:2)(44:24)
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admit (52:12)
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advise (33:6)(36:23)
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advising (28:15)(35:23)
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afford (57:16)
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although (24:6)
always (46:13)
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becomes (26:24)
becoming (62:7)
been (6:21)(7:19)(10:5)(11:4)(11:18)(13:2)(15:18)(28:19)(37:6)(37:7)(38:14)(47:24)(50:22)
before (1:14)(9:5)(12:4)(17:24)(23:17)(27:13)(28:19)(30:7)(33:21)(43:7)(44:2)(49:20)(52:3)(57:10)
began (27:6)
begin (9:7)
beginning (10:11)
behalf (1:19)(2:6)(3:7)
behind (8:23)
being (4:19)(14:17)(25:23)(27:4)(34:14)(34:15)(61:13)(62:7)
believe (10:17)(24:15)(36:17)
believed (25:22)
bench (12:10)
best (19:12)
between (29:16)(36:8)(44:1)(45:17)(46:21)
beyond (15:14)
bhatt (2:19)(4:2)
big (52:13)
bill (4:1)
bilson (2:2)(3:21)(3:22)
bit (5:24)(6:2)(6:19)(18:19)(59:14)
blanket (36:3)(54:16)
both (4:23)(9:5)(19:6)(33:24)(43:14)(45:16)(46:6)(47:7)(54:13)(55:24)(59:22)(60:16)
bound (21:23)(23:8)(25:23)(26:8)(26:9)(26:19)(34:14)(34:16)(35:3)(42:14)(42:16)
box (41:8)(41:9)
branded (20:12)
breach (28:7)
brief (9:8)(53:2)
briefed (20:8)
briefing (20:2)(37:1)(60:22)(61:1)
briefly (38:7)
briefs (30:8)(60:4)
bring (7:11)(57:8)
broaden (46:14)
brought (38:20)
burden (31:3)(31:6)(37:18)(41:15)(49:18)(49:19)(50:14)(50:17)(50:19)(50:21)(51:1)
business (20:13)(21:2)(22:22)(24:2)(24:8)(25:7)(25:12)(25:17)(27:5)(32:9)(38:12)
but (4:17)(7:19)(8:9)(9:3)(11:4)(11:12)(12:5)(15:9)(16:10)(16:23)(17:4)(19:8)(19:14)(22:8)(23:18)(24:4)(24:6)(24:9)(24:21)(25:13)(35:3)(37:14)(39:16)(40:2)(43:11)(43:16)(44:10)(46:8)(46:13)(46:18)(47:14)(48:3)(48:7)(48:13)(48:18)(50:20)(52:4)(54:4)(54:9)(54:22)(56:5)(56:18)(57:12)(57:15)(58:6)(59:14)(60:21)(62:6)

C

calendar (19:3)(19:6)(19:10)(19:16)(19:19)(59:12)(59:14)
california (51:16)
call (12:17)(48:10)
called (9:10)
calling (11:19)
calls (18:7)
came (14:18)
camp (45:21)(45:22)
can (5:12)(5:14)(6:20)(7:21)(8:6)(8:16)(9:1)(10:13)(13:15)(17:6)(17:9)(18:2)(19:2)(19:3)(19:11)(19:12)(19:13)(19:23)(25:16)(26:17)(27:20)(31:21)(32:3)(34:2)(35:2)(36:23)(41:6)(43:6)(44:18)(44:21)(54:17)(57:10)(58:13)(58:15)(59:7)(59:20)
candor (23:4)
cannot (25:17)(32:6)(32:8)(46:10)(55:2)
can't (12:9)(12:16)(30:16)(34:13)(36:5)(46:14)
carroll (63:3)(63:16)(63:17)
carve (50:23)
carve-out (51:5)(54:5)(55:22)
carves (51:15)
carving (27:20)
case (4:14)(4:18)(5:1)(8:22)(9:9)(9:20)(10:1)(10:5)(20:19)(30:15)(32:19)(36:24)(37:8)(37:16)(40:19)(41:21)(44:11)(47:1)(47:17)(50:16)(51:5)(52:17)(53:8)(53:10)(54:1)(54:14)(55:2)(55:12)(56:1)(58:14)(61:20)(63:12)
case-by-case (11:23)(39:6)(45:19)(54:16)
cases (28:20)(36:10)(38:9)
cat (44:3)(57:10)
catch (51:10)
caught (56:19)
cause (50:15)(50:20)
causes (40:8)
certain (8:16)(17:22)(22:4)(24:9)(25:11)(57:4)(57:20)
certainly (25:3)(26:17)(27:2)(31:11)(43:5)
certify (63:4)(63:7)
cetera (22:20)
chad (1:18)(3:8)(5:11)
challenge (54:8)
challenging (52:3)(52:7)
chambers (44:17)(57:1)(61:3)
chance (13:22)
change (47:20)(49:1)(53:14)
changing (48:19)(48:24)
characterization (53:18)
charts (33:16)(33:21)(36:20)
check (19:18)(39:18)
christie (3:24)
christy (2:5)
circuit (49:15)(49:17)
circumstance (27:23)
circumstances (11:24)(25:13)(27:10)(36:2)(41:1)
cite (36:21)(37:5)
cited (37:17)(38:11)(51:12)
citing (16:6)(33:18)
claim (33:16)(33:21)(48:19)(49:7)(53:11)(53:14)(53:21)
claimant (36:20)
claims (32:4)(46:15)(47:19)(47:20)(48:20)(49:1)(49:2)(54:10)(55:2)
clear (42:13)

clearly (58:16)
clerk (19:18)
client (20:24)(28:16)(39:20)(40:6)
clients (3:13)(52:13)
clients' (23:20)
code (34:15)(47:2)(47:4)(47:6)(47:11)(52:12)(55:12)(56:9)
cold (6:1)
collaborating (20:20)
colleague (3:8)
collection (43:1)(43:2)
come (7:21)(7:23)(13:8)(13:24)(14:3)(37:14)(43:24)(52:11)(53:19)(61:24)
comes (9:24)(24:21)(30:10)(36:10)
comfort (25:22)
comfortable (59:15)
coming (11:21)(12:13)(17:7)(26:21)(53:4)
comments (17:16)
communicate (32:24)(35:13)
communicates (24:22)(24:24)
communication (35:12)(39:20)
companies (20:13)
company (9:15)(20:15)(27:15)(31:13)(32:17)
compel (60:24)
competition (20:22)
competitive (20:17)(24:16)(25:4)(25:13)(25:20)(31:2)(31:7)(31:11)(31:14)(31:16)(31:18)(31:21)(36:12)(37:15)(38:10)(40:23)(49:21)(49:24)(53:12)(53:20)(56:10)
competitor (28:4)
complete (49:8)(49:13)(51:24)
completely (20:20)(30:4)
complicated (23:12)
complied (15:18)
compromise (23:16)
concern (5:17)(21:1)(26:6)(27:1)(27:12)(27:16)(28:6)(30:1)(34:20)(39:10)(40:8)(41:4)(42:21)(46:9)(57:5)(58:5)
concerned (6:2)(28:2)(38:1)
concerning (8:14)
concerns (13:16)(14:20)(15:4)(17:16)(27:6)(34:1)(41:7)(41:11)(43:4)(43:17)(43:24)(56:6)(56:8)(58:5)
concluded (59:15)(62:12)
conclusion (55:8)
condition (35:5)(39:7)(42:4)
conditions (23:2)(23:14)(26:18)(29:18)(29:21)(30:19)(34:9)(34:18)(34:23)(41:17)(42:14)
conduct (22:19)(23:9)(26:10)(26:20)(34:5)(34:15)(39:17)(42:17)(59:22)
confer (44:15)
conference (4:6)(4:9)(9:2)(39:23)
conferences (61:15)
confidential (8:16)(21:2)(22:4)(23:20)(24:6)(27:24)(28:3)(28:17)(28:24)(30:12)(32:18)(33:4)(33:11)(33:12)(33:17)(33:19)(34:3)(35:9)(35:13)(35:22)(36:21)(37:3)(37:21)(38:17)(38:18)(39:21)(40:22)(42:7)(42:12)(43:18)(43:20)(43:21)(46:10)(46:17)(49:3)(54:21)(55:5)(55:11)(57:6)(58:6)
confirm (60:1)
conflict (45:23)
connections (43:13)
consent (29:24)
consider (57:13)(58:15)
consideration (40:18)(40:20)
considered (55:24)
consistent (57:2)(57:23)(58:8)
constitute (53:12)
consultant (55:10)
consulting (55:18)
contact (11:4)(12:19)(13:2)(31:12)
contains (38:17)
contention (45:17)
contentions (5:16)(15:16)(36:24)(39:11)(39:12)
continued (2:1)
continuing (52:22)
contract (34:24)(35:2)(35:3)(35:5)
contracts (13:6)
contractual (13:4)
contrary (58:17)
control (7:20)
convenient (5:13)(59:19)
conveniently (11:20)
conversation (17:14)
conversations (41:22)(48:15)
convinced (56:5)
copy (32:19)(33:20)
core (5:15)
corp (40:19)
corporate (4:7)(8:15)(21:23)(41:23)
correct (21:17)(51:16)(53:7)
corrected (38:20)
correction (51:9)
correspondence (29:16)
could (9:13)(33:21)(47:7)(50:8)(52:15)
counsel (3:14)(3:16)(3:17)(3:24)(4:11)(8:11)(10:13)(17:23)(18:2)(19:4)(19:11)(21:7)(21:14)(21:15)(22:10)(23:10)(24:13)(25:10)(25:11)(26:2)(26:7)(26:22)(27:8)(28:15)(29:10)(30:23)(30:24)(31:17)(32:3)(32:22)(33:6)(34:4)(34:7)(38:8)(38:11)(38:12)(39:2)(39:13)(39:14)(40:16)(44:9)(47:17)(47:21)(48:9)(48:10)(48:11)(53:7)(54:6)(54:9)(57:19)(61:17)(63:8)(63:12)
counsel's (39:17)(41:2)(41:11)(41:20)(53:17)
country (27:4)(27:17)(27:21)(43:4)
couple (6:4)(38:8)(47:7)
course (6:14)(16:11)(36:16)(40:1)(40:7)(42:22)(44:1)
court (1:1)(1:14)(3:1)(3:19)(4:4)(5:21)(6:16)(7:7)(8:3)(8:11)(10:15)(11:12)(11:16)(11:19)(12:18)(12:24)(13:17)(14:6)(15:12)(15:19)(16:15)(16:17)(17:13)(17:24)(18:22)(19:17)(20:9)(21:13)(21:22)(21:24)(22:4)(22:20)(24:14)(25:21)(25:24)(26:1)(27:11)(29:4)(29:12)(30:10)(30:20)(32:13)(33:3)(33:23)(34:17)(35:18)(36:4)(38:5)(39:16)(40:10)(40:14)(43:4)(45:3)(45:13)(47:9)(48:2)(48:6)(49:4)(50:4)(50:11)(51:5)(51:18)(51:21)(52:9)(53:1)(53:6)(53:23)(57:9)(58:4)(61:9)(61:12)(61:19)(63:4)
courtroom (1:11)(4:1)(59:24)(60:10)
court's (22:18)(32:16)(42:5)(42:19)
covered (18:16)
cow (28:10)
cower (41:10)
crafted (29:2)
create (26:11)
creating (17:21)
criminal (59:9)(59:12)(59:14)
crop (59:6)
cropped (7:3)
cross-examination (27:18)
current (10:23)(12:20)(13:5)
currently (10:23)

D

daily (32:23)(32:24)
date (9:3)(17:6)(17:22)(19:3)(19:5)(19:9)(19:16)(19:18)(19:23)(59:7)(59:9)(60:1)(60:3)(61:22)
dates (15:18)
david (2:2)(3:22)
day (28:13)(39:10)(53:19)
deadlines (4:20)(5:1)
deal (36:10)
dealing (44:13)
dealt (30:16)(37:10)
decision (12:5)(25:13)(46:19)(49:15)
decision-making (24:17)(31:2)(31:8)(31:11)(31:14)(31:16)(31:18)(31:22)(32:9)(36:12)(37:16)(38:10)(40:24)(49:22)(49:24)(53:12)(53:20)(56:10)
decisions (12:9)(12:12)(25:4)(25:5)(25:20)(45:24)(48:12)(54:15)(55:24)(57:16)
declaration (24:19)(31:9)

defend (54:8)
defendant (5:14)(9:21)(34:14)(47:16)
defendants (1:7)(2:6)(3:20)(3:23)(5:22)(6:1)(7:1)(13:20)(34:11)(57:5)(57:8)(61:10)
defendant's (15:15)(55:5)(59:3)
defendants' (14:10)(60:9)
defense (41:20)(42:1)
deficiency (18:24)
definitive (7:15)
degree (40:24)
delaware (1:2)(1:12)(10:4)(11:20)(23:8)(42:16)
dense (47:4)
depending (30:14)
deposition (7:13)(7:18)(10:21)(11:11)(11:21)(13:3)(14:4)(19:7)
depositions (10:18)(11:7)(13:11)(13:14)(14:7)(18:3)(18:4)(27:14)(30:9)(58:24)(60:8)
deputy (59:24)(60:11)
derail (5:1)
described (48:12)
designated (8:17)(24:15)(33:9)(33:15)(38:14)(38:16)(43:20)
designation (21:17)
desire (46:21)(46:23)
details (24:21)
deutsche (49:16)(50:16)(51:2)(53:8)
developed (9:9)
developing (57:21)
development (38:2)(38:3)
diclofenac (32:6)(32:10)
did (6:4)(9:24)(10:3)(33:3)(37:5)(51:5)(51:8)(51:10)(60:4)
didn't (37:11)(48:24)
difference (22:12)(26:12)(36:8)(47:14)(49:12)
different (6:12)(11:1)(20:21)(21:20)(21:21)(21:22)(22:11)(27:8)(50:6)(55:8)(61:1)
differently (6:2)
difficult (14:3)(23:14)(44:5)(46:15)
diligence (10:3)
direct (20:22)(20:24)(27:17)(28:3)
directly (20:17)
disagree (16:21)(45:8)(53:17)
disclose (35:14)(37:12)
disclosure (28:7)(41:5)(41:8)(42:23)(43:9)
disclosures (43:22)
discovery (1:10)(4:6)(4:9)(4:12)(4:13)(4:15)(4:17)(4:23)(5:6)(5:7)(5:13)(6:3)(6:9)(6:21)(8:6)(8:12)(8:21)(8:23)(9:2)(10:6)(10:7)(10:9)(13:18)(14:11)(14:20)(15:13)(16:1)(16:12)(16:16)(17:18)(19:21)(19:22)(42:24)(43:3)(44:8)(57:23)(58:21)(58:22)(60:6)(61:15)(61:16)(61:19)(61:21)
discrete (43:5)(57:13)
discuss (8:10)(13:22)(19:19)(40:5)(40:6)(48:9)
discussed (5:5)(5:19)(58:23)
discussion (13:17)
discussions (13:19)
dispute (14:15)(15:8)(21:9)
disputes (8:6)(8:12)(8:23)(58:23)(61:24)
distance (62:4)
distinct (43:16)
distinction (27:22)
distinguish (49:11)
district (1:1)(1:2)(1:14)(11:19)(49:13)(50:3)(51:4)(51:16)(58:14)
districts (51:13)
divest (54:23)
docket (44:18)
document (6:21)(6:23)(10:8)(10:9)(16:7)(16:8)(16:12)(18:11)(18:12)(18:20)(27:2)(39:21)(43:1)
documents (5:15)(6:14)(6:15)(8:17)(16:6)(16:24)(18:14)(18:21)(21:3)(26:13)(29:23)(34:20)(36:1)(36:17)(36:19)(38:2)(43:2)
does (24:22)(32:22)(34:11)(41:14)(52:2)(53:19)(62:5)
doesn't (22:10)(28:9)
doing (13:13)
domestic (52:4)
don't (5:16)(6:17)(13:6)(14:4)(19:20)(20:6)(25:6)(28:14)(28:21)(30:5)(33:23)(36:17)(38:22)(39:9)(39:14)(40:2)(40:3)
doubt (52:1)
dovetails (25:9)
down (14:18)(17:16)(26:16)(28:19)(36:10)(42:21)(53:19)
draft (44:13)(54:3)(61:5)
drafting (47:19)(54:10)
draw (27:19)(47:3)
drew (21:12)
drug (9:15)(9:16)(20:12)(20:15)
due (10:3)
during (32:1)(37:12)(42:21)(43:24)(53:11)
duties (22:19)(23:3)
duty (59:9)

E

each (7:2)(10:6)(14:22)(41:1)(54:23)(58:7)(58:9)(60:15)
easiest (10:16)
easy (10:23)(47:3)(47:6)
effort (22:24)(23:15)
efforts (17:21)
either (7:21)(20:6)(26:23)(33:1)(57:18)(58:12)(58:20)
elizabeth (1:18)(3:6)
else (22:16)(37:2)
elsewhere (56:18)
email (14:19)(15:1)(33:1)
emails (18:8)
employed (27:15)(63:9)(63:12)
employee (10:24)(31:1)(32:17)(63:11)
employees (11:2)(12:20)(13:5)(13:6)(28:1)(31:13)
enable (13:7)
end (14:15)(28:5)(28:12)(39:9)(53:19)
ended (29:9)
enforcement (34:17)(42:19)
engaging (61:17)
enjoy (23:22)
enlarged (55:2)
enough (31:14)
enter (44:18)
entered (31:4)
entire (22:16)(33:9)(33:15)
entity (20:18)
erroneous (58:17)
esq (1:18)(2:2)(2:5)
essence (22:13)(26:20)
ethical (22:19)(25:15)(25:23)(26:3)(26:7)
ethically (34:6)
ethics (23:4)(34:16)
even (6:8)(12:19)(16:24)(17:9)(21:15)(31:13)(32:5)(33:21)(38:4)(47:5)(48:10)(50:9)
event (22:1)(57:3)
ever (48:8)
every (15:2)(33:2)(35:12)(35:23)(39:19)(39:22)
everyone (3:2)(47:5)
everyone's (13:16)
evidence (31:7)
exact (39:1)
exactly (39:4)(49:23)(53:13)
example (6:10)(59:12)
exception (38:11)
exchange (44:1)
exchanged (4:19)(6:21)
exchanges (14:22)(42:24)
excuse (5:24)
executives (31:13)(33:7)
exemption (49:18)(50:23)(51:1)
exhibit (29:14)(30:11)(41:18)(42:15)(51:17)(51:20)
exists (46:13)(46:14)
expect (16:3)(43:18)(56:23)
experience (16:3)

experts (55:19)
explain (6:11)(17:1)(30:1)
explained (16:22)
explaining (31:10)
extent (35:12)(46:8)(47:19)(47:23)(48:7)(48:14)
extra (60:19)

F

facilitate (62:1)
fact (4:12)(15:13)(22:2)(23:12)(23:22)(30:2)(30:15)(32:21)(45:18)(56:1)(60:11)(61:18)
factual (41:1)
fair (47:14)(48:10)
fairly (45:5)
fairness (58:3)
faith (4:19)
fallon (1:11)(1:14)
familiar (12:6)(44:10)
far (13:19)(15:23)(18:2)(38:15)
fashion (4:24)(41:23)
fathom (34:13)
fda (32:7)
federal (49:15)(49:17)
feel (58:8)
field (20:21)(55:16)
figure (12:7)
figuring (11:5)
file (15:15)
filed (9:16)(10:4)(48:1)
filing (33:2)
finally (18:17)
financially (63:12)
find (23:11)
fine (26:24)
first (5:8)(5:9)(6:18)(14:13)(16:19)(17:15)(17:21)(17:23)(19:24)(21:18)(26:15)(26:18)(35:14)(45:2)(53:3)
fish (1:17)(3:6)
five (6:7)(10:19)
five-day (12:10)
fixed (38:21)
flagged (29:6)(56:17)
flanagan (1:18)(3:5)(3:6)(3:12)
flow (16:11)
focus (46:3)
focused (45:5)
following (50:17)
foot (6:3)
footing (21:21)
for (1:2)(3:3)(3:15)(3:16)(3:18)(3:19)(3:23)(4:6)(4:10)(6:7)(6:10)(6:11)(6:22)(7:13)(7:18)(9:12)(9:17)(9:22)(10:18)(10:21)(11:10)(11:13)(11:21)(13:1)(13:3)(14:1)(14:3)(15:2)(16:2)(16:22)(17:2)(19:10)(20:23)(23:19)(23:20)(24:2)(27:13)(27:17)(27:18)(33:6)(33:20)(35:16)(41:4)(49:8)(49:13)(50:5)(50:15)(54:22)(55:16)(56:15)(57:8)(58:22)(59:11)(59:12)(60:13)(60:21)(61:3)(61:13)(61:14)(63:8)
force (7:21)(13:4)(13:7)
forced (46:5)
foregoing (63:4)(63:5)
foreign (52:4)
foreseeable (20:23)
form (53:15)
formal (42:11)
former (13:5)
formula (50:8)
formulation (47:11)(50:5)(50:6)(52:11)
formulations (32:5)
forth (51:23)(54:2)
forum (61:24)
forward (19:20)(41:21)(57:22)
found (22:13)
four (11:1)(11:3)(11:5)(12:19)(16:13)(34:24)(52:23)(60:5)
fourth (12:21)
frame (13:12)
frankly (9:23)
free (40:5)
friday (38:21)
from (3:6)(3:22)(3:24)(4:2)(5:1)(5:9)(5:18)(5:22)(6:18)(7:1)(8:7)(9:5)(15:21)(16:16)(17:18)(18:19)(18:23)(20:1)(21:23)(22:4)(22:17)(30:21)(32:17)(37:2)(40:18)(45:22)(48:20)(49:5)(50:16)(51:13)(52:17)(53:9)(54:5)(54:6)(55:13)(55:18)(57:20)(60:15)(61:7)(61:9)(61:16)(62:8)
front (29:8)(46:11)
full (11:24)
fully (25:6)(28:17)
functions (22:9)
further (8:20)(9:6)(15:13)(15:19)(15:21)(16:8)(38:6)(40:10)(55:17)(61:7)(61:9)(63:7)(63:10)
future (9:3)(16:18)(20:23)

G

gave (47:16)
general (3:14)(3:15)(3:17)(4:11)(15:14)(15:24)(54:16)(57:16)
generalize (54:4)
generally (14:19)(16:11)(21:1)(25:1)
generic (9:15)(9:18)(20:15)(32:5)(32:10)(37:22)
get (8:2)(13:23)(14:23)(17:18)(19:2)(34:8)(35:15)(56:23)(59:23)(61:22)
gets (41:8)
getting (7:3)(15:20)(44:6)(44:16)(60:15)
give (9:5)(12:5)(40:17)(45:13)(47:15)(48:21)(59:7)(61:4)
given (28:3)
giving (11:16)(19:22)(60:19)
global (43:12)
goes (35:16)
going (7:11)(8:12)(9:4)(12:8)(12:12)(14:16)(17:6)(17:17)(18:4)(18:13)(19:15)(23:22)(27:13)(27:15)(30:10)(35:8)(42:2)(42:8)(47:20)(48:2)(51:6)(55:21)(56:11)(57:22)(60:6)(60:12)(60:15)
goldman (2:2)(3:22)
gone (15:2)
good (3:1)(3:5)(3:10)(3:21)(4:4)(4:19)(50:15)(50:20)
got (13:19)
gotten (7:15)
govern (41:3)
granted (37:6)
groups (24:23)(24:24)
guess (15:24)(26:14)(59:10)
guidance (40:17)(45:14)(61:4)
guide (29:4)(52:18)
guidelines (60:22)
guidepost (12:7)

H

had (4:5)(13:21)(14:6)(14:20)(14:24)(18:7)(18:9)(21:16)(23:1)(26:3)(33:10)(33:19)(52:20)
hague (7:14)(7:17)(8:1)(11:6)(11:8)(11:9)(17:12)
hampered (14:17)
hand (20:12)(20:14)(41:13)(46:4)
handle (5:12)(8:6)
hands (57:18)
hang (51:18)
happen (10:10)(18:4)(41:12)(42:23)
happening (28:18)
happens (28:9)
happy (15:10)(59:17)
hard (41:9)
harm (35:1)(50:3)
has (5:14)(9:12)(9:16)(10:5)(10:13)(20:24)(31:3)(31:9)(32:15)(37:6)(45:9)(50:14)(50:19)(50:21)(52:20)
hasn't (37:7)(47:24)
hatch-waxman (9:20)
hate (57:11)
have (3:12)(3:14)(3:15)(3:16)(4:8)(4:14)(5:4)(5:16)

(5:17)(5:23)(5:24)(6:3)(6:12)(7:5)(7:10)(7:14)(7:17)
(7:19)(7:20)(7:24)(8:16)(10:6)(11:10)(11:12)(12:4)
(12:10)(12:19)(13:2)(13:3)(13:6)(13:12)(13:19)(14:4)
(15:7)(15:18)(16:7)(16:17)(17:6)(17:14)(18:7)(18:9)
(18:17)(19:15)(20:4)(20:12)(20:14)(20:17)(21:7)(21:11)
(22:10)(23:7)(23:14)(23:15)(24:3)(24:4)(24:8)(24:11)
(24:12)(24:13)(24:14)(25:15)(25:21)(26:12)(27:1)(28:9)
(28:14)(28:19)(28:21)(29:5)(31:6)(32:17)(32:19)(32:22)
(33:4)(33:7)(33:13)(34:2)(34:4)(34:22)(35:14)(37:2)
(37:10)(37:14)(37:17)(37:22)(38:13)(38:14)(39:10)
(39:14)(39:18)(39:20)(40:21)(41:22)(42:3)(42:8)(43:3)
(43:12)(43:13)(43:15)(44:4)(44:14)(45:14)(45:16)
(45:18)(48:4)(48:12)(48:14)(50:7)(50:20)(51:21)(51:22)
(52:20)(52:21)(52:22)(53:3)(53:24)(54:15)(55:23)(59:7)
(59:9)(59:13)(59:21)(61:23)
haven't (13:21)(17:5)(37:20)(38:3)
having (23:16)(31:12)(36:4)(39:23)(40:15)(40:16)
(41:12)(41:15)(42:20)(49:2)(55:23)(58:10)
hear (5:9)(5:21)(6:18)(6:19)(7:1)(8:13)(8:21)(9:4)
(16:16)(19:24)(30:21)(49:5)
heard (17:4)(40:15)
hearing (1:10)(5:5)(17:4)(19:20)(20:11)(34:1)(43:5)
(45:15)(58:22)(59:10)(59:23)(62:5)
hearings (60:12)
heart (28:6)
help (47:22)(62:1)
helpful (19:15)(36:7)
her (25:7)(25:24)(26:12)(26:22)(28:17)(31:10)(32:23)
(32:24)(33:5)(33:6)(34:4)(37:18)(37:19)(40:5)
here (4:8)(6:12)(6:24)(10:4)(10:20)(12:16)(13:8)
(14:3)(17:17)(21:6)(22:2)(22:15)(31:2)(36:8)(44:9)
(44:20)(45:14)(49:19)(49:22)(50:20)(52:13)(53:5)
(53:14)(61:14)(62:4)(62:6)(62:7)
herself (25:5)(26:10)(42:5)
he's (10:22)(10:23)
hicks (59:24)(60:11)
highly (21:2)(33:12)(33:16)(38:16)(38:17)(55:11)
him (12:23)(14:3)
his (10:21)(16:20)
historical (38:1)(38:2)
history (15:15)
holdings (51:3)
honor (3:6)(3:11)(3:22)(5:11)(5:20)(5:24)(7:6)(8:5)
(16:19)(17:3)(18:6)(19:14)(20:7)(23:17)(24:19)(25:8)
(26:16)(26:21)(27:23)(28:5)(29:9)(29:15)(29:19)(30:22)
(31:23)(32:14)(32:20)(37:5)(38:8)(40:12)(45:1)(49:11)
(50:4)(51:8)(52:10)(52:17)(53:3)(61:8)(61:11)(62:10)
(62:11)
honorable (1:14)
hope (18:1)(19:13)
hoping (29:3)
horse (41:10)
how (4:11)(6:24)(8:24)(9:6)(13:18)(14:21)(15:13)
(17:18)(19:22)(20:4)(21:22)(28:9)(29:2)(34:19)(35:18)
(35:19)(36:7)(36:9)(47:9)(59:22)(60:13)(60:14)(61:5)
(61:18)
however (38:10)
hypothetical (47:24)

I

iceutica (1:3)(2:18)(3:3)(3:7)(3:15)(9:9)(20:12)
i'd (8:21)
identify (47:6)
i'm (5:4)(8:12)(11:22)(13:7)(16:22)(19:5)(19:8)
(19:17)(24:19)(25:5)(34:1)(34:8)(35:20)(36:7)(37:8)
(37:11)(37:24)(44:8)(44:20)(45:2)(48:10)(50:11)(50:16)
(52:1)(55:21)(56:5)(56:11)(56:14)(59:15)(59:17)(60:15)
immediate (9:12)(21:1)
immediately (16:6)
impede (33:5)(41:20)
implicate (49:21)(56:10)
importantly (39:1)
imposed (22:1)
in the (55:17)
inadvertent (28:8)(41:4)(41:7)(42:22)(43:9)(43:22)
(46:16)
inadvertently (46:5)
inappropriate (56:9)
include (42:4)(42:10)(50:13)(51:7)(51:14)(52:2)(54:1)
(55:22)
included (42:11)
includes (51:23)(54:4)
including (49:9)(52:4)(52:15)
inclusion (50:15)
inconsistent (46:6)(46:22)
incorporated (56:22)
incorporates (44:18)(44:19)
incredibly (14:3)(46:15)
independent (26:23)
india (8:15)(21:16)(27:4)(28:10)(29:1)(35:7)(36:17)
indicating (36:1)
indication (9:6)
individual (41:2)
individuals (17:19)(55:13)
infancy (16:1)
inform (26:2)
information (14:4)(22:5)(23:21)(24:9)(25:19)(27:3)
(27:16)(27:20)(27:24)(28:3)(28:17)(28:22)(28:24)(31:5)
(32:18)(33:4)(33:11)(33:18)(33:19)(34:3)(35:9)(35:13)
(35:24)(36:22)(37:3)(37:21)(38:3)(38:18)(40:22)(42:9)
(42:13)(43:10)(43:15)(43:17)(43:20)(44:1)(46:10)
(46:17)(46:23)(49:3)(54:21)(55:5)(57:6)(58:6)
informed (34:4)
infringement (5:16)(15:16)(33:16)(33:20)(36:20)
(36:23)(39:11)(50:3)
infringing (35:10)
inhouse (21:7)(21:14)(21:15)(21:17)(22:8)(22:9)
(22:21)(23:3)(23:10)(24:13)(25:10)(25:11)(26:7)(27:5)
(27:8)(29:10)(30:24)(31:17)(31:20)(32:2)(32:22)(34:4)
(34:7)(36:18)(39:23)(40:20)(57:19)
initial (10:3)(10:6)(10:7)(15:16)
initiated (20:1)(57:4)
inserted (56:14)
inside (59:1)
instance (14:14)(30:17)(55:21)(56:6)(60:5)
instances (43:6)(56:14)(57:13)
instead (47:22)
institute (32:11)
instituted (48:8)
insufficient (14:16)
intend (35:15)(37:3)
intent (4:22)(5:3)
intents (9:17)
inter (52:6)
interest (23:20)
interested (63:13)
interim (19:12)(59:6)
interrogatories (6:5)(6:7)(6:9)(6:22)(14:9)(16:4)
(16:10)(59:4)(60:10)
interrogatory (6:10)(18:9)(18:10)(33:10)
into (13:19)(19:23)(23:10)(35:2)(40:24)(41:9)(41:10)
(60:12)
introduce (3:13)
introductions (3:3)
intrusion (39:17)
inventor (11:4)(51:3)
inventors (7:8)(7:21)(10:18)(10:19)(13:23)(14:1)
(17:3)(17:7)(18:8)(27:14)(27:18)(59:1)(59:2)
invested (61:16)(62:7)
involve (31:10)(34:12)
involved (16:23)(24:16)(25:4)(25:5)(25:12)(31:2)
(31:7)(31:15)(31:18)(31:21)(36:12)(40:23)(48:19)
(53:14)(53:22)
involves (12:13)(40:24)(55:4)
involving (32:6)
ipr (40:13)(47:24)(48:8)(49:10)(50:24)(51:7)(51:15)
iroko (2:18)(3:4)(3:8)(3:16)(3:18)(9:9)(20:12)
irrelevant (55:6)

irreparable (34:24)
isn't (22:22)(24:1)(39:16)(40:5)
issue (5:19)(7:3)(7:6)(12:1)(14:8)(14:11)(15:21)(20:2)(20:3)(20:18)(27:12)(29:20)(30:15)(34:7)(36:10)(36:24)(38:23)(44:3)(44:22)(45:5)(45:15)(46:3)(47:2)(54:1)(55:13)(55:16)
issued (49:15)(52:20)
issues (4:13)(4:15)(5:8)(5:18)(6:4)(8:8)(8:13)(8:18)(8:20)(10:8)(10:12)(15:10)(15:19)(15:21)(16:17)(17:19)(18:1)(19:6)(19:7)(19:21)(19:24)(20:8)(26:15)(35:6)(37:8)(37:11)(40:15)(44:8)(45:18)(58:20)(59:5)(60:6)(60:7)(62:1)
issuing (44:12)(58:19)
item (29:22)
itemized (15:3)
its (21:2)(49:15)(50:15)
it's (4:9)(4:18)(4:24)(11:8)(11:18)(14:16)(17:5)(18:22)(19:23)(26:24)(29:10)(29:14)(29:19)(30:13)(30:15)(30:24)(35:7)(40:7)(40:9)(41:9)(46:15)(47:6)(47:13)(48:10)(50:24)(52:7)(52:12)(59:18)(62:4)
itself (12:2)(22:2)(54:22)(56:4)
i've (41:18)(54:12)(56:16)(56:19)(57:2)

J

james (2:17)(3:15)
job (14:2)(32:22)
jointly (35:1)
judge (1:11)(32:15)(54:13)(54:19)(58:14)(59:9)(62:6)
judicial (52:17)
july (19:9)
june (1:9)
jurisdiction (21:24)(22:3)(22:18)(26:1)(32:12)(34:17)(42:6)(42:18)
just (6:13)(6:17)(8:21)(12:7)(14:2)(16:23)(17:5)(18:6)(18:23)(22:14)(22:17)(22:22)(26:21)(27:12)(27:23)(34:10)(34:11)(36:4)(38:7)(39:2)(40:9)(42:13)(44:10)(46:21)(51:7)(51:11)(53:2)(56:15)(60:14)(60:21)(61:2)

K

keep (12:8)(29:11)
keeping (28:17)(43:17)
kenexa (45:16)(45:21)(46:8)(46:20)(49:11)(54:13)(54:19)(55:1)
key (27:22)(47:14)
kind (5:2)(28:10)(37:12)(39:1)(39:4)(39:5)
kinds (30:9)(39:12)(48:17)
king (1:12)
knobbe (2:4)(3:24)
know (14:1)(17:7)(25:16)(32:14)(50:8)(52:13)(52:14)(58:11)(60:13)(60:14)(61:19)(61:23)
knowing (39:22)
knows (18:7)

L

laid (29:15)
language (55:23)(56:12)(56:14)(56:21)
larisha (59:24)(60:11)
last (10:17)(16:20)(30:15)
lastly (38:24)
later (19:19)
law (19:17)(37:16)(58:17)
lawsuit (10:11)(28:18)(52:19)(52:21)
lawyers (42:17)
lea (2:5)(4:1)(5:23)(6:17)(7:5)(7:8)(16:19)(18:6)(19:13)(30:22)(34:22)(36:6)(40:5)(49:6)(50:18)(51:20)(51:22)(52:10)(61:11)(62:10)
lead (44:16)
least (18:2)(32:16)
leave (27:20)(29:23)(36:2)(59:22)
leaves (35:24)
leaving (27:3)(34:20)(43:4)
led (48:4)
left (12:9)
legal (8:15)(40:20)
lend (12:2)
lengthy (14:23)(14:24)(18:10)
lesser (46:7)
let (5:9)(5:21)(6:16)(6:18)(9:7)(16:15)(29:18)(30:1)(30:20)(45:13)(49:4)(51:18)
let's (3:2)(20:3)
letter (10:3)(15:7)(51:10)(60:4)
letters (14:23)
level (25:21)(56:6)(56:7)
liable (35:1)
license (22:10)(26:4)(26:8)
licensed (21:19)(22:15)(23:5)(23:24)(26:10)
licensees (6:13)
licensure (22:13)(25:14)
like (8:7)(8:10)(8:21)(9:4)(17:13)(17:22)(23:9)(32:20)(43:23)(50:24)(51:7)(51:11)(52:12)(60:12)(60:14)
likelihood (46:16)
likely (19:8)(42:23)(43:8)(49:21)
limited (1:6)(2:19)(24:9)(25:16)(29:10)(32:21)(49:7)(51:14)(52:5)(60:5)
line (17:16)(21:12)(27:19)(42:21)(46:2)(47:3)(52:1)
lines (58:23)
lingering (12:9)
listed (23:7)
litigate (41:21)(58:7)
litigation (6:20)(9:19)(9:23)(25:2)(33:7)(36:13)(37:18)(39:18)(41:22)(42:22)(43:12)(47:4)(47:17)(47:20)(48:8)(57:20)(57:21)(57:24)(62:2)
litigations (24:23)
litigators (48:24)
little (5:24)(6:1)(6:19)(18:19)(45:14)
live (43:11)
llp (2:4)
locate (11:5)(12:23)
located (10:20)(10:22)(21:15)
location (10:18)(10:21)
locations (56:20)
long (62:4)
longer (12:20)(27:14)
look (23:6)(46:18)(51:19)(61:4)
looking (50:12)
looks (47:5)
lot (45:15)
ltd (1:3)(2:18)
lupin (1:6)(2:19)(3:20)(3:23)(4:2)(9:15)(16:16)(24:10)(24:11)(24:16)(28:19)(29:17)(29:20)(30:2)(30:17)(30:21)(32:21)(35:23)(37:10)(49:5)(50:5)(56:7)
lupin's (8:15)(26:2)(26:22)(27:5)(28:15)(33:22)(38:17)(46:9)(47:10)

M

made (12:12)(16:7)(37:20)(38:3)(54:15)(57:2)
magistrate (1:14)
make (4:17)(8:13)(16:8)(42:13)(43:8)(51:8)(57:16)(61:2)
makes (23:13)
making (4:23)(11:22)(12:5)(20:13)(20:15)(25:19)(36:3)(44:8)(44:20)(58:2)
manage (33:5)
management (24:24)(25:2)(37:15)(52:17)
manager (36:9)
managing (36:13)
manner (57:23)
manning (2:17)(3:14)
many (18:11)(18:20)(60:14)
marked (30:12)(56:15)
market (9:18)
marketed (9:10)
maron (3:17)
martens (2:4)(3:24)
martha (2:17)(3:14)
material (47:12)
materials (21:11)(24:3)(24:7)(30:18)(35:22)(39:3)

(40:7)(43:2)(45:10)(57:22)
matter (17:5)(28:9)(32:21)(36:15)
may (4:13)(7:6)(7:18)(8:23)(14:10)(16:17)(24:8)
(25:11)(25:19)(46:2)(49:16)(52:8)(54:9)(62:5)
maybe (10:16)(34:11)(35:18)(38:11)(56:17)
meaningful (41:24)
means (13:18)
measure (21:4)(23:19)(23:21)(48:22)
medication (9:11)
meet (4:20)(44:15)(47:15)
meet-and-confer (15:1)(15:5)(18:10)(18:15)(37:13)
meeting (5:1)
mentioned (5:20)(10:17)
met (31:6)(37:17)
might (24:13)(25:18)(27:9)(33:24)(36:6)(37:1)(47:22)
(48:9)(48:15)(56:9)(59:5)(59:13)
mini (2:19)(4:2)
minimal (6:9)
minimized (43:21)
misstatement (51:9)
misused (22:5)
modify (58:15)
moji (2:17)(3:15)
monday (1:9)
monitoring (61:20)
months (9:22)(16:13)(32:2)
moran (2:17)
more (7:6)(14:6)(23:13)(36:6)(42:23)(43:8)(44:5)
(46:2)(49:13)(52:23)(53:3)(55:8)(59:18)(60:6)
morning (3:1)(3:5)(3:21)(4:4)(8:8)(38:22)
motions (60:24)
move (19:20)(40:13)
much (9:20)(23:13)(38:22)(47:6)(60:13)
multiple (18:7)(18:8)(60:17)
must (41:3)
myriad (10:10)

N

naidu (24:22)(25:22)(26:2)(26:8)(29:18)(31:5)(32:23)
(33:22)(35:7)(35:14)(36:8)(36:22)(37:4)(37:6)(39:4)
(39:10)(42:3)
nature (24:7)(25:6)
necessary (11:6)(11:9)(43:7)
necessity (60:23)
need (8:1)(12:12)(15:10)(17:14)(17:20)(22:7)(43:14)
needed (22:1)
needs (17:24)(39:13)(56:21)(60:17)
negotiation (10:9)
neither (63:7)
new (9:16)(14:2)(20:13)
next (44:22)
nexus (22:7)
night (38:21)
nine (30:13)
nonattorney (24:12)(30:24)(31:15)(36:11)
nondispositive (58:11)
none (6:5)(11:2)(31:10)(31:20)(32:2)
nonetheless (43:16)
nonevent (10:22)
non-practicing (20:18)
nor (63:8)(63:12)
normal (16:11)
northern (51:16)
not (4:8)(4:24)(5:4)(7:15)(7:17)(7:19)(8:14)(11:22)
(12:1)(13:5)(13:24)(14:20)(15:23)(17:1)(17:9)(17:10)
(17:11)(18:13)(18:21)(19:8)(19:17)(20:18)(20:19)
(21:10)(21:14)(22:21)(23:12)(24:6)(24:10)(24:19)(25:5)
(25:22)(27:9)(27:15)(27:21)(28:8)(30:13)(30:15)(31:6)
(31:14)(32:22)(33:4)(35:5)(35:8)(35:20)(36:2)(36:7)
(36:9)(36:13)(36:16)(37:8)(37:11)(37:15)(37:17)(37:24)
(38:12)(41:12)(42:10)(42:23)(43:8)(44:6)(44:12)(45:9)
(46:21)(46:23)(47:5)(47:21)(48:10)(49:1)(49:7)(49:21)
(50:2)(50:17)(51:5)(51:10)(51:15)(52:2)(52:4)(52:13)
(53:5)(53:13)(53:22)(54:6)(54:9)(56:2)(56:3)(56:5)
(56:15)(57:18)(58:19)(62:4)(63:11)
notably (39:14)
notary (63:18)
note (24:1)
noted (38:8)(55:1)
notice (52:23)
notification (19:1)(29:22)
noting (20:11)
november (12:11)
now (10:12)(14:17)(15:4)(15:8)(20:22)(21:4)(23:11)
(29:8)(46:12)(50:22)(53:7)(60:21)
number (34:8)(35:6)(60:19)(60:23)
nutshell (40:9)

O

object (34:14)(58:12)
objection (34:23)
objections (58:15)
objective (57:24)
objectives (58:9)
obligations (22:18)(22:19)(25:15)(25:23)(26:3)(26:7)
(26:9)(26:11)(42:7)
observe (34:6)
observed (11:18)
obtain (54:21)
obviously (10:20)(14:15)(21:9)(25:2)(45:5)
occur (17:23)(43:10)
occurred (9:13)
occurrence (41:12)
occurring (49:14)
odds (43:7)
off (6:3)
office (35:8)(35:9)(46:11)(49:20)(50:9)
okay (5:21)(7:5)(10:15)(12:24)(16:15)(30:11)(45:3)
(51:19)(52:9)
olsen (2:4)
once (9:12)(10:2)(41:7)(44:14)
one (7:6)(10:19)(11:4)(11:17)(14:1)(16:7)(20:3)
(20:11)(20:19)(21:20)(24:13)(26:18)(32:16)(35:7)(37:5)
(38:11)(38:16)(38:19)(40:15)(44:15)(45:2)(46:4)(46:21)
(51:8)(51:17)(56:24)
one-paragraph (14:19)(15:1)
ones (56:16)(56:19)
only (5:19)(8:12)(52:7)(55:4)
onset (9:12)
onto (42:12)
open (43:5)
operate (47:7)
operated (30:7)
operates (14:21)
opinions (54:13)
opportunity (4:10)
oppose (21:14)
opposed (26:22)(34:10)(48:13)
opposing (17:23)(39:19)(40:21)
order (4:16)(4:21)(5:2)(5:4)(5:6)(5:8)(5:20)(7:4)
(8:7)(8:14)(10:14)(12:8)(15:20)(19:24)(20:2)(20:7)
(21:5)(21:8)(22:6)(23:23)(24:4)(28:8)(29:6)(29:8)
(29:19)(30:19)(31:4)(31:19)(32:1)(37:5)(37:10)(37:19)
(41:16)(42:4)(42:19)(44:12)(44:14)(44:17)(44:19)(45:6)
(45:10)(50:13)(51:17)(53:16)(54:3)(56:13)(56:18)
(56:22)(57:1)(58:16)(58:19)(58:20)(58:21)
orders (51:13)
organization (25:18)
other (8:23)(11:1)(11:18)(13:20)(14:5)(14:8)(15:20)
(20:14)(21:3)(24:7)(24:23)(24:24)(28:20)(31:12)(38:9)
(38:19)(41:13)(44:16)(46:22)(51:13)(54:17)(54:23)
(55:10)(56:20)(56:24)(59:5)(60:16)(60:17)
otherwise (34:13)
our (3:13)(4:7)(5:18)(9:18)(10:3)(14:15)(17:11)
(19:20)(23:20)(27:2)(27:24)(28:1)(28:2)(28:23)(33:17)
(33:19)(35:8)(35:9)(35:11)(37:22)(38:20)(39:11)(40:7)
(45:15)(48:20)(52:11)
ours (38:18)

out (7:24)(11:6)(12:7)(12:18)(14:24)(18:2)(19:12)(19:14)(27:17)(27:20)(29:15)(30:13)(41:8)(43:15)(44:3)(44:6)(51:3)(51:11)(51:15)(53:4)(56:15)(57:10)
outcome (56:4)
outset (20:11)(27:7)(39:5)
outside (28:15)(33:5)(40:8)(43:13)(54:6)(54:9)(58:24)
outstanding (14:9)
over (7:20)(16:13)(21:3)(59:13)
overarching (5:3)
overdesignating (33:9)(35:22)
overdesignation (38:13)
overly (41:19)
overseas (21:16)(28:4)
oversight (38:19)
overview (19:22)
own (33:19)

P

page (56:17)
pages (60:5)(60:19)
pain (9:11)(9:12)
papers (12:4)
paragraph (10:2)(29:13)(30:6)(35:4)(51:20)(51:23)(52:2)
paramount (43:19)
part (11:14)(47:18)(47:21)(58:16)
parte (52:5)
partes (52:6)
participate (32:3)(32:7)(32:8)(45:11)(52:8)(54:9)
participating (54:6)(55:14)(55:19)
particular (43:1)(43:3)(43:24)(55:16)
particularly (12:13)
parties (4:11)(4:19)(5:4)(5:17)(6:12)(9:5)(10:5)(10:24)(11:3)(14:23)(16:1)(20:8)(20:20)(20:22)(21:4)(21:6)(29:9)(29:16)(36:5)(43:12)(43:19)(44:2)(44:15)(45:5)(49:18)(50:12)(50:20)(53:24)(56:23)(57:17)(57:19)(58:4)(59:8)(59:18)(59:19)(60:24)(63:9)
parties' (8:24)(34:1)
party (22:2)(41:3)(50:18)(50:22)(52:3)(52:7)(54:20)(58:9)(60:17)(61:13)
party's (40:22)(58:7)
patent (8:17)(9:19)(32:4)(46:11)(49:20)(50:9)(52:3)(52:8)(52:17)(54:8)(54:10)(55:4)(55:9)(55:14)
patent prosec (47:23)
patents (7:9)(10:19)(52:20)(53:4)
patents-in-suit (55:17)
pending (6:22)(6:24)
people (13:4)(23:23)(24:8)(25:3)(25:12)(25:17)(31:12)(38:13)(39:24)
percolating (4:14)(8:24)
perfectly (8:9)
perhaps (10:13)(19:2)(20:7)(22:9)(26:21)
permissible (16:5)(22:8)
permission (9:17)(35:16)
permit (40:20)(56:11)
person (9:2)(21:16)(22:21)(22:22)(23:3)(23:9)(23:12)(24:2)(27:5)(55:11)(59:17)(59:23)
personal (32:12)
perspective (5:18)(45:23)(48:20)
pharmaceuticals (3:16)(3:18)(4:3)
pharmacopeia (32:8)
philadelphia (10:22)
phillips (2:2)(3:22)
phone (7:16)(14:23)(18:7)(33:1)(59:23)
piece (35:13)(35:24)
place (7:4)(11:8)(28:7)(54:18)(56:3)
placed (23:15)
places (46:6)
plaintiff (3:3)(15:21)(31:3)(35:15)(41:14)(49:19)(59:5)
plaintiffs (1:4)(1:19)(3:7)(5:9)(6:5)(6:19)(7:10)(8:4)(12:20)(17:14)(20:1)(33:8)(34:10)(35:4)(35:21)(36:1)(37:9)(41:19)(43:3)(50:7)(55:22)(61:7)
plaintiff's (9:23)
plaintiffs' (34:20)(41:6)(42:14)(45:22)(51:10)(54:2)(54:4)(56:12)(60:9)
plan (36:16)(36:19)(36:22)
play (47:18)(47:21)
please (3:2)(60:10)
pleasure (3:13)
plenty (61:3)
point (16:23)(37:15)(40:11)(40:18)(47:10)(51:11)
points (7:2)(17:15)(17:24)(38:8)(47:8)(53:2)
portions (54:3)
position (21:13)(24:20)(25:10)(46:4)
positions (46:6)(46:22)(48:15)
posted (60:22)
post-grant (44:24)(45:12)(46:12)(49:9)(50:10)(52:16)(53:6)(54:7)(55:15)(55:20)(56:2)(57:4)
post-surgical (9:13)
potential (22:3)
potentially (46:5)
practical (36:15)
practice (12:6)(14:21)(32:16)(44:9)
practiced (30:7)
precise (16:4)
preclude (54:6)
precluded (55:13)
predictability (58:3)
predominantly (9:11)
preemptively (57:9)
preference (20:4)(59:21)
prejudice (57:8)
premature (15:9)
prepared (8:9)(9:21)
preparing (42:1)
present (2:16)
presently (56:2)
presents (21:19)
preview (11:17)(14:10)
previously (4:8)(37:6)
primary (40:18)(40:19)
prior (29:23)(48:16)(55:5)
probably (12:6)(18:16)
problem (11:15)(26:12)(28:14)(28:21)(30:14)(38:21)(39:14)
procedure (46:12)
proceed (6:18)(9:6)(44:21)(59:20)(60:21)
proceeding (6:24)(48:13)(49:9)(55:15)(55:20)(61:21)(63:6)(63:10)
proceedings (50:10)(54:7)(54:11)(56:3)(57:4)(57:7)(62:12)
process (4:12)(11:6)(15:4)(61:18)(62:8)
produce (11:21)(18:13)(18:21)
produced (5:15)(5:16)(6:14)(57:23)
producing (21:1)
product (9:10)(9:19)(30:3)(35:11)(37:21)(37:23)
production (10:9)(15:2)(15:15)(16:8)(16:12)(18:11)(18:12)(27:2)
productions (16:9)
products (20:14)(20:16)
professional (23:9)(26:19)(34:5)(34:15)(42:17)(63:3)(63:18)
progress (62:1)
progressed (19:23)
progresses (4:24)
progressing (4:12)(10:5)(15:14)(16:14)
prohibited (55:9)(55:17)
prohibiting (31:4)
prohibition (36:4)
promised (15:6)
prompting (8:22)
proportional (4:18)
proposal (54:2)(54:4)
proposals (42:15)
proposed (23:1)(26:18)(56:12)
proprietary (21:2)
prosecute (52:22)

prosecuting (32:4)
prosecution (8:17)(44:23)(45:7)(45:8)(45:21)(48:9)(48:11)(48:13)(49:6)(49:8)(49:14)(50:14)(50:19)(50:21)(50:23)(51:6)(51:14)(51:22)(51:24)(52:1)(52:15)(53:4)(53:5)(53:11)(53:24)(54:5)(55:9)(55:15)(55:19)
prosecutors (50:7)(52:14)
protect (42:12)
protecting (58:6)(58:7)
protection (21:4)(23:19)(23:21)(47:16)(48:22)(56:6)
protections (26:5)(33:24)(54:18)(54:20)(57:17)
protective (4:15)(5:8)(5:20)(7:4)(8:14)(15:20)(19:24)(20:2)(21:5)(21:8)(22:6)(23:23)(24:3)(28:8)(29:6)(29:7)(29:19)(30:19)(31:4)(31:19)(32:1)(37:5)(37:10)(37:19)(41:16)(42:4)(42:19)(44:13)(44:17)(44:19)(45:6)(45:10)(50:13)(51:13)(53:16)(54:3)(56:13)(56:18)(56:22)(57:1)
protest (52:5)
provide (19:18)(25:1)
providing (40:7)
provision (29:22)(50:13)
provisions (29:11)
pty (1:3)(2:18)
public (37:22)(63:18)
publicly (48:16)
purpose (61:14)
purposes (9:18)(27:17)(56:16)
pursuant (42:3)
pursuing (57:20)
put (23:1)(23:2)(23:10)(28:10)(45:21)(49:17)
putting (54:18)(57:12)

Q

question (26:15)(27:7)(37:18)(48:3)
quick (38:8)
quickly (7:24)
quote (37:2)(53:9)(53:10)

R

raised (8:8)(10:13)(14:8)(15:5)(29:20)(30:2)(56:7)
rather (22:22)(35:23)(36:3)
reached (55:7)
read (29:5)(41:18)(45:16)(53:9)
reading (39:11)
real (27:11)
realize (55:7)(62:3)
really (28:12)(30:8)(34:12)(38:22)(39:7)(39:12)(40:9)(41:14)(48:23)(62:6)
reason (24:14)
rebuttal (38:6)
receive (18:19)(18:24)
received (10:2)(14:19)(52:23)
recent (48:11)
recognize (25:10)(58:5)
recognized (54:14)
record (32:15)(56:16)
recourse (28:10)
redacted (33:20)
redesignate (33:14)
reduce (60:19)
re-exam (51:7)(51:15)
re-examination (49:10)(50:24)(52:6)(55:3)(55:4)(55:6)
reference (6:15)
referenced (22:14)(27:23)(53:8)
referencing (29:11)
referring (37:9)
regard (7:3)(8:20)(14:8)(14:11)(15:13)(16:16)(44:7)(56:8)(59:2)
regarding (14:7)
regular (31:12)
reissue (52:5)
related (5:8)(63:8)
relates (44:23)
relating (4:15)(32:4)(44:22)
relationship (41:3)
relative (58:20)(63:11)
released (37:22)
relied (6:8)(6:13)
relief (9:12)
remaining (5:19)
repeat (44:10)
repeatedly (7:10)
reporter (63:4)(63:18)
reporting (36:14)
representation (49:20)
representations (42:11)
representative (2:19)(8:15)(21:23)(24:15)(33:22)(34:2)(36:11)(36:18)(39:21)(40:23)(41:23)
representatives (2:18)(4:7)(31:21)(32:3)(40:21)(61:13)
represented (18:23)
representing (52:3)
request (15:2)(30:10)
requests (6:22)(6:23)(18:12)(18:20)
require (26:1)(30:3)(34:6)
required (32:11)(42:7)
requirement (22:14)
requirements (25:14)
resolve (23:16)
resort (7:14)(7:17)(8:1)
respect (32:9)(39:2)(40:2)
respective (54:23)
responded (10:6)(27:9)
responding (60:16)
response (15:6)(16:4)(18:24)(19:3)(33:10)
responses (14:12)(14:15)(18:9)(18:11)(19:8)(59:3)(60:9)
responsibilities (25:7)
restrictions (41:15)
restrictive (41:14)(41:19)(55:8)
retained (57:18)
reverse (10:14)
reversed (9:21)
review (1:10)(4:6)(4:9)(5:7)(5:13)(26:23)(39:13)(53:6)(54:7)(55:15)(56:2)(57:4)(61:15)
reviewed (27:5)(29:1)(40:16)(55:24)
reviewing (18:18)(26:13)(36:19)(54:12)
reviews (33:2)
revised (44:17)(56:21)(57:1)
richardson (1:17)(3:7)
right (4:5)(6:16)(12:24)(15:4)(15:8)(15:12)(29:4)(29:8)(30:23)(49:4)(50:18)(53:1)(53:23)(60:21)
rights (24:12)(54:22)(54:24)(58:7)
rise (56:7)
risks (43:21)
road (26:16)(28:19)
robinson (32:15)(54:19)
robinson's (54:13)
role (37:18)
roles (9:20)
rule (6:8)(6:13)(16:4)(16:21)(40:14)(54:17)(58:12)
rules (22:17)(23:8)(26:19)(26:23)(34:5)(42:17)
ruling (11:17)(11:22)(12:2)(44:12)
rulings (8:13)(44:7)(44:14)(44:19)(57:2)(57:7)(58:2)(58:11)(58:13)
run (59:13)

S

safe (57:12)
safeguards (31:24)
said (12:18)(13:2)(14:18)(18:16)(30:17)(33:17)(33:18)(35:4)(39:5)(42:20)(43:23)(49:23)(51:2)(51:6)(54:19)(56:11)(58:10)
same (13:12)(21:11)(22:23)(23:3)(23:10)(23:21)(24:6)(24:12)(28:20)(30:23)(47:16)(48:22)(51:4)
sample (51:12)
sanctions (22:1)(22:3)
satisfied (50:22)
say (5:14)(14:7)(15:24)(24:22)(31:14)(37:4)(37:9)(51:14)(52:19)

saying (27:9)(35:21)(47:17)(53:13)(53:21)
says (30:11)(31:19)(35:5)(50:12)(51:4)(51:24)
scant (24:21)
schedule (61:2)
scheduled (4:5)
scheduling (4:21)(5:2)(12:8)(13:11)(18:3)
scientist (24:2)
scope (45:8)(48:20)(48:24)(49:2)(53:11)(53:15)(53:19)(53:21)(55:2)
search (10:10)(16:2)(18:17)
seated (3:2)
second (15:22)(24:5)(27:1)
secret (52:13)
see (4:11)(6:1)(12:3)(22:7)(29:5)(30:11)(35:6)(35:8)(35:10)(36:7)(43:19)
seeing (61:20)
seek (23:19)(60:24)(61:1)
seeking (9:17)(49:18)(50:12)(50:19)(57:17)
seeks (24:10)(24:11)
seems (13:9)(13:14)
send (33:21)(36:19)(36:22)(56:24)
sense (13:23)(19:21)(41:19)(58:3)
sensitive (27:3)(27:16)
sent (19:1)(27:4)(29:17)(30:12)(36:20)
separate (22:17)
series (5:12)
serve (6:4)(44:11)(58:19)
served (10:6)(59:4)
set (9:1)(16:12)(19:3)(19:5)(19:10)(19:16)(22:16)(41:15)(51:23)(54:2)(58:15)(58:21)(59:11)(60:13)
setting (59:16)
seven (23:1)(23:6)(29:2)(29:11)(34:9)(41:17)
several (3:13)(56:13)
severally (35:1)
shape (53:15)
share (25:17)(25:18)(28:1)(30:3)(30:18)(31:5)(37:4)(39:3)(58:4)
she (10:17)(19:18)(24:22)(24:23)(25:2)(25:4)(26:3)(26:10)(26:19)(26:24)(31:7)(31:9)(33:2)(33:3)(34:6)(36:23)(39:12)(40:6)(42:5)(42:6)(42:7)(42:8)(42:12)(42:13)(42:16)(42:18)(55:1)(55:7)(55:13)
shear (1:18)(3:9)(3:10)(5:11)(5:12)(8:4)(8:5)(9:7)(10:16)(11:14)(12:15)(12:22)(13:1)(13:21)(14:13)(15:17)(15:23)(18:23)(20:3)(20:6)(20:10)(21:18)(22:12)(24:18)(26:14)(27:22)(29:7)(29:14)(35:19)(38:6)(38:7)(40:1)(40:12)(45:1)(45:4)(46:1)(47:13)(48:4)(48:7)(53:1)(53:2)(53:7)(61:8)(62:11)
sherry (1:11)(1:14)
she's (35:8)(36:13)
ship (36:16)
shipped (28:24)
shocking (18:19)
should (9:1)(9:6)(11:20)(17:23)(21:7)(21:10)(24:1)(31:4)(35:19)(36:2)(45:11)(48:4)(54:20)(54:22)(58:12)
show (31:3)(49:19)(50:19)(51:1)
showing (37:20)(38:4)(50:15)
shown (31:6)
side (9:24)(13:20)(14:22)(21:3)(39:19)(44:16)(56:24)(57:18)(58:12)(60:16)(60:17)
sides (4:23)(9:5)(43:14)(59:22)(60:16)
side's (46:21)(46:23)
sign (42:12)
simple (32:21)
simply (4:9)(5:14)(18:12)(18:21)(37:17)
since (10:5)(20:1)(44:13)(52:19)(59:8)
single (15:2)(30:16)(33:2)
sit (7:13)(7:18)(11:10)(11:13)(13:3)(17:10)
sitting (17:11)(36:18)
situation (13:10)(13:15)(20:21)(21:20)(22:24)(24:8)(28:2)(28:20)(29:3)(33:8)(33:12)(34:13)(35:20)(40:4)(44:5)(50:4)
situations (9:14)(20:19)
small (9:8)(46:17)
some (4:14)(12:4)(21:3)(23:19)(27:12)(33:24)(40:17)(50:23)(54:12)(61:4)
someone (21:10)(22:8)(29:1)(34:14)(34:15)(34:16)(45:9)
something (7:24)(12:3)(17:8)(19:10)(26:17)(37:2)(41:13)(44:4)
somewhat (49:12)(51:9)
somewhere (22:16)(42:21)
sore (24:21)
sorry (50:11)(50:16)
sort (22:24)(23:3)(28:10)(38:24)
sounds (17:13)(26:6)
source (47:2)(47:4)(47:5)(47:11)(52:12)(55:11)(55:12)(56:8)
speak (22:9)(28:11)(32:23)(41:8)(44:4)(57:11)
specific (6:23)(10:12)(15:9)(16:24)(43:6)(43:17)(45:19)(57:13)
specifically (14:1)(29:5)(44:23)(45:9)(47:2)(53:9)
spence (2:2)(3:23)
spent (27:12)(54:12)
spot (23:10)
square (46:19)
stacked (43:8)
stand (12:16)
standard (30:23)(31:1)
standards (22:23)(54:18)
standing (6:11)(16:22)(17:1)
stands (29:8)(53:16)
start (3:2)(20:5)(20:7)(26:16)(59:10)(60:2)(61:16)(62:8)
started (8:2)(14:2)(20:10)(49:14)(52:20)
stated (32:15)
statement (16:20)(47:14)
states (1:1)(1:14)(7:12)(7:22)(7:23)(17:8)(34:21)(36:1)(36:3)(43:14)(43:15)(59:1)(59:2)
stating (14:19)
status (12:21)
stay (43:20)
steel (40:19)
still (13:22)(15:24)(24:6)(36:7)
stood (49:22)
stop (6:17)
story (11:2)
strategic (21:21)
strategically (53:10)
strategy (41:22)(52:16)(57:21)
streamline (60:18)
street (1:12)
strictly (29:10)
strong (59:21)
structure (50:1)
stuart (2:17)(3:17)
stuff (41:9)
subject (21:24)(22:3)(22:16)(22:23)(25:24)(42:5)
submission (41:18)(42:15)
submissions (32:7)(60:15)(60:18)(60:20)(61:5)
submit (32:12)(42:18)(60:4)
submitted (24:20)(31:9)(33:3)
submitting (22:17)(34:16)
subset (24:9)(27:2)
substantive (33:10)
substantively (6:6)
such (43:17)(54:10)(54:20)(55:19)
sufficiency (14:11)(19:7)(59:3)(60:8)
suggested (26:21)(34:9)(55:23)
suit (10:4)
sunday (38:21)
supplemental (16:9)
support (24:20)
sure (4:17)(4:23)(5:4)(5:23)(9:7)(14:13)(16:19)(16:22)(19:17)(22:12)(24:19)(25:6)(34:2)(35:20)(36:7)(37:8)(37:24)(47:13)(48:10)(56:15)(61:2)
surprise (9:24)
surprised (14:14)
surrendering (53:11)
surrounding (41:1)

system (24:5)

T

table (3:24)
take (7:2)(11:23)(16:20)(20:3)(44:16)(46:6)(46:22)(48:16)(51:18)(58:13)(61:4)
taken (28:1)(52:16)(63:10)
takes (28:7)
taking (11:7)(13:18)(18:3)(27:16)(56:3)
talk (38:9)(48:15)
talked (46:21)(60:7)
talking (13:23)(27:13)(28:16)(38:12)(39:2)(39:15)(53:5)
taneha (63:3)(63:17)
target (4:20)(61:22)
tasks (31:10)
team (47:4)
technical (5:15)
technology (55:16)
teleconference (9:3)(59:20)(59:21)
tell (7:10)(7:20)(8:11)(12:16)(17:6)(34:12)(45:20)
ten (30:13)
tend (40:14)
tentatively (59:11)
terms (10:10)(16:2)(18:17)(18:18)(34:24)(41:13)
testify (17:17)
than (15:20)(35:23)(36:3)(36:9)(42:23)(43:8)(44:6)(46:2)(50:6)(54:17)(60:7)
thank (3:19)(30:20)(38:5)(45:1)(48:6)(53:22)(61:12)(61:13)(62:8)(62:10)(62:11)
that (4:5)(4:13)(4:17)(4:18)(4:22)(4:23)(5:3)(5:10)(5:12)(6:2)(6:23)(7:3)(7:16)(7:24)(8:6)(8:7)(8:12)(8:23)(9:4)(9:6)(9:16)(10:4)(10:10)(10:12)(10:22)(11:19)(12:1)(13:1)(13:6)(13:7)(13:9)(13:15)(14:10)(14:17)(15:5)(15:7)(15:10)(16:17)(16:21)(17:10)(17:19)(17:22)(18:1)(18:2)(18:20)(18:23)(19:1)(19:2)(19:4)(19:9)(19:19)(20:11)(21:5)(21:7)(21:15)(21:16)(21:18)(21:19)(21:20)(21:22)(22:2)(22:10)(22:14)(22:15)(23:2)(23:4)(23:7)(23:10)(23:12)(23:13)(23:15)(23:17)(23:21)(23:22)(23:23)(24:1)(24:7)(24:9)(24:13)(24:15)(24:19)(24:22)(25:3)(25:8)(25:10)(25:11)(25:22)(26:6)(26:7)(26:11)(26:16)(26:17)(26:18)(26:21)(26:24)(27:1)(27:11)(27:15)(28:7)(28:21)(29:11)(29:20)(29:22)(30:2)(30:5)(30:6)(30:9)(30:17)(30:19)(31:3)(31:6)(31:7)(31:15)(31:16)(31:20)(31:24)(32:14)(32:15)(32:18)(32:19)(32:21)(32:22)(33:3)(33:13)(33:24)(34:6)(34:7)(35:3)(35:6)(35:15)(35:16)(35:24)(36:6)(36:17)(36:22)(36:23)(36:24)(37:1)(37:8)(37:15)(37:16)(38:9)(38:11)(38:14)(39:1)(39:4)(39:5)(39:10)(39:16)(40:2)(40:4)(40:8)(40:9)(40:17)(40:22)(40:24)(41:7)(41:9)(41:12)(41:18)(41:24)(42:2)(42:5)(42:6)(42:7)(42:8)(42:12)(42:13)(42:15)(42:16)(42:17)(42:20)(42:22)(43:3)(43:6)(43:8)(43:11)(43:13)(43:18)(43:19)(43:21)(43:24)(44:5)(44:8)(44:15)(44:17)(44:18)(44:19)(44:20)(44:21)(45:2)(45:6)(45:8)(46:9)(46:16)(46:18)(46:20)(46:23)(47:1)(47:10)(47:15)(47:17)(47:21)(48:3)(48:5)(48:7)(48:14)(48:21)(49:14)(49:19)(49:24)(50:2)(50:6)(50:8)(50:21)(51:1)(51:5)(51:10)(51:13)(51:14)(51:17)(52:8)(52:11)(52:13)(52:14)(52:16)(52:21)(53:15)(53:18)(53:21)(54:14)(54:17)(54:20)(55:7)(55:23)(56:1)(56:3)(56:5)(56:9)(56:14)(56:16)(56:21)(56:23)(57:2)(57:3)(57:10)(57:11)(57:14)(57:16)(57:17)(57:22)(58:4)(58:10)(58:16)(59:4)(59:5)(59:7)(59:9)(59:13)(59:22)(59:24)(60:7)(60:11)(60:19)(60:22)(61:1)(61:3)(61:6)(61:15)(61:17)(61:19)(61:20)(61:21)(61:23)(62:1)(63:4)(63:7)(63:10)
that's (5:2)(6:21)(6:24)(10:16)(11:14)(13:11)(13:13)(14:17)(19:11)(21:11)(24:4)(28:11)(29:2)(30:5)(36:9)(37:3)(40:3)(48:23)(50:15)(51:1)(51:15)(51:17)(52:7)(53:4)(53:13)(59:18)
the (1:1)(1:2)(1:14)(3:1)(3:3)(3:7)(3:12)(3:19)(3:20)(4:1)(4:4)(4:5)(4:10)(4:12)(4:15)(4:17)(4:19)(4:20)(4:22)(5:1)(5:2)(5:3)(5:4)(5:5)(5:6)(5:7)(5:8)(5:13)(5:14)(5:17)(5:18)(5:19)(5:21)(5:22)(6:1)(6:3)(6:7)(6:8)(6:11)(6:16)(6:18)(6:20)(6:21)(7:7)(7:8)(7:11)(7:14)(7:16)(7:17)(7:20)(7:22)(7:23)(8:1)(8:3)(8:5)(8:11)(8:12)(8:13)(8:14)(8:17)(8:18)(8:22)(8:24)(9:5)(9:9)(9:20)(9:21)(9:22)(9:23)(10:2)(10:4)(10:5)(10:7)(10:10)(10:11)(10:12)(10:15)(10:17)(10:18)(10:19)(10:20)(10:21)(10:24)(11:1)(11:3)(11:5)(11:6)(11:7)(11:8)(11:9)(11:12)(11:15)(11:16)(11:17)(11:24)(12:1)(12:5)(12:8)(12:18)(12:20)(12:21)(12:24)(13:1)(13:5)(13:10)(13:11)(13:12)(13:13)(13:15)(13:17)(13:19)(13:20)(13:23)(13:24)(14:1)(14:5)(14:6)(14:7)(14:8)(14:11)(14:13)(14:15)(14:18)(14:21)(14:23)(15:1)(15:3)(15:4)(15:8)(15:12)(15:15)(15:19)(15:20)(15:24)(16:1)(16:11)(16:12)(16:15)(16:16)(16:17)(16:18)(16:22)(16:24)(17:3)(17:7)(17:8)(17:12)(17:13)(17:16)(17:24)(18:3)(18:8)(18:10)(18:11)(18:12)(18:15)(18:16)(18:20)(18:22)(18:24)(19:3)(19:5)(19:6)(19:7)(19:10)(19:12)(19:14)(19:16)(19:17)(19:19)(19:21)(19:22)(19:23)(20:1)(20:2)(20:7)(20:8)(20:9)(20:10)(20:11)(20:13)(20:14)(20:20)(20:21)(20:23)(21:3)(21:4)(21:6)(21:8)(21:9)(21:12)(21:13)(21:22)(21:24)(22:2)(22:4)(22:5)(22:7)(22:12)(22:13)(22:18)(22:19)(22:24)(23:3)(23:6)(23:8)(23:10)(23:12)(23:13)(23:21)(23:22)(23:23)(24:6)(24:7)(24:12)(24:14)(24:18)(24:19)(24:21)(25:1)(25:6)(25:14)(25:17)(25:21)(25:24)(26:1)(26:3)(26:6)(26:13)(26:15)(26:16)(26:18)(26:19)(26:23)(27:1)(27:3)(27:7)(27:9)(27:11)(27:12)(27:15)(27:17)(27:19)(27:20)(27:22)(27:23)(28:2)(28:5)(28:6)(28:7)(28:10)(28:11)(28:12)(28:13)(28:18)(28:20)(29:2)(29:3)(29:4)(29:5)(29:7)(29:9)(29:10)(29:12)(29:15)(29:16)(29:19)(29:21)(29:23)(30:1)(30:2)(30:6)(30:9)(30:10)(30:15)(30:18)(30:20)(30:23)(31:1)(31:3)(31:13)(31:15)(31:17)(31:19)(31:20)(32:1)(32:2)(32:3)(32:5)(32:7)(32:12)(32:13)(32:15)(32:17)(32:18)(32:20)(32:21)(33:3)(33:6)(33:7)(33:8)(33:20)(33:23)(33:24)(34:3)(34:5)(34:10)(34:20)(35:8)(35:12)(35:18)(35:21)(35:24)(36:2)(36:4)(36:5)(36:7)(36:9)(36:11)(36:13)(36:20)(36:23)(36:24)(37:8)(37:14)(37:16)(37:17)(37:18)(37:19)(38:5)(38:10)(38:13)(38:18)(38:21)(39:1)(39:3)(39:4)(39:5)(39:9)(39:12)(39:16)(39:17)(39:19)(39:20)(40:7)(40:8)(40:10)(40:13)(40:14)(40:15)(40:16)(40:19)(41:1)(41:8)(41:10)(41:11)(41:12)(41:14)(41:17)(41:18)(41:21)(42:1)(42:3)(42:4)(42:6)(42:11)(42:14)(42:18)(42:19)(42:21)(42:22)(42:24)(43:4)(43:7)(43:13)(43:15)(43:18)(43:21)(43:24)(44:1)(44:2)(44:3)(44:6)(44:7)(44:15)(44:16)(44:18)(44:19)(44:21)(44:22)(45:3)(45:5)(45:8)(45:10)(45:13)(45:17)(45:20)(45:21)(45:23)(46:3)(46:8)(46:11)(46:12)(46:14)(46:16)(46:18)(46:22)(47:1)(47:2)(47:4)(47:5)(47:9)(47:14)(47:15)(47:16)(47:17)(47:19)(47:23)(48:2)(48:6)(48:7)(48:11)(48:14)(48:16)(48:19)(48:20)(48:21)(48:24)(49:1)(49:2)(49:4)(49:6)(49:10)(49:12)(49:13)(49:15)(49:17)(49:18)(49:19)(49:20)(50:3)(50:5)(50:6)(50:9)(50:11)(50:14)(50:16)(50:18)(50:19)(50:20)(51:4)(51:16)(51:18)(51:21)(52:7)(52:9)(52:12)(52:17)(52:21)(53:1)(53:6)(53:8)(53:9)(53:10)(53:11)(53:16)(53:19)(53:20)(53:23)(54:1)(54:3)(54:5)(54:8)(54:9)(54:13)(54:14)(54:17)(55:1)(55:2)(55:3)(55:4)(55:6)(55:12)(55:16)(55:18)(55:22)(55:24)(56:1)(56:4)(56:6)(56:7)(56:12)(56:13)(56:16)(56:18)(56:19)(56:22)(56:23)(56:24)(57:2)(57:3)(57:5)(57:8)(57:9)(57:10)(57:16)(57:17)(57:18)(57:19)(57:22)(57:24)(58:4)(58:5)(58:8)(58:12)(58:13)(58:14)(58:16)(58:19)(58:21)(58:23)(58:24)(59:1)(59:2)(59:3)(59:4)(59:6)(59:7)(59:8)(59:10)(59:14)(59:18)(59:19)(60:1)(60:3)(60:5)(60:7)(60:8)(60:16)(60:17)(60:19)(60:22)(60:23)(60:24)(61:7)(61:9)(61:10)(61:12)(61:13)(61:15)(61:16)(61:18)(61:19)(61:20)(62:1)(62:2)(62:6)(62:8)(62:12)(63:4)(63:5)(63:9)
their (5:15)(6:11)(17:1)(18:17)(24:20)(25:17)(26:8)(28:16)(30:3)(33:9)(33:15)(35:15)(36:16)(36:21)(37:2)(37:21)(38:1)(38:2)(41:22)(46:10)(46:23)(49:2)(49:20)(50:2)(50:3)(50:7)(50:8)(50:24)(52:13)(52:14)(52:15)(54:23)(57:24)
them (6:11)(7:11)(7:21)(8:10)(9:1)(10:13)(10:20)(11:2)(11:21)(13:7)(15:6)(15:11)(18:5)(18:18)(18:19)

(19:1)(30:3)(33:13)(36:5)(39:22)(46:16)(47:15)(48:11)
(48:21)(55:18)(56:15)(57:14)(60:13)
themselves (23:11)(35:4)(57:20)
then (7:2)(14:16)(19:21)(30:10)(31:17)(35:5)(38:24)
(50:24)(51:24)(56:22)(60:3)(61:2)
theory (17:1)
there (6:17)(10:19)(13:9)(13:14)(14:10)(14:14)(16:23)
(19:21)(25:11)(26:14)(31:24)(37:7)(38:13)(38:23)
(42:20)(42:24)(43:14)(43:16)(43:23)(44:3)(47:24)
(49:17)(56:2)(56:4)(56:13)(56:20)(57:3)(57:5)(58:2)
(60:6)(60:18)(61:6)(61:24)
there's (15:9)(24:5)(38:22)(45:17)(49:12)(51:9)(54:16)
these (8:23)(11:23)(13:4)(17:19)(18:1)(26:9)(26:11)
(29:18)(30:19)(34:9)(38:9)(39:15)(40:15)(41:15)(44:8)
(45:18)(54:15)(57:7)(57:15)(58:2)(58:11)(58:20)(60:12)
they (6:8)(6:13)(7:9)(7:11)(7:12)(7:17)(7:19)(7:20)
(7:21)(7:22)(11:9)(11:12)(11:21)(12:19)(13:2)(13:5)
(13:24)(14:20)(15:6)(17:5)(17:9)(18:12)(18:13)(18:15)
(18:20)(20:1)(23:7)(23:22)(24:20)(25:15)(25:16)(25:18)
(29:15)(30:14)(30:17)(31:1)(31:5)(31:6)(32:6)(32:8)
(33:9)(33:15)(33:18)(36:20)(36:21)(37:9)(37:11)(37:17)
(37:20)(38:3)(38:11)(38:20)(39:3)(39:18)(39:19)(41:20)
(41:24)(45:6)(46:1)(47:7)(48:21)(48:23)(49:23)(50:1)
(50:23)(51:6)(51:12)(51:13)(52:12)(52:20)(52:21)
(52:22)(52:23)(54:22)(55:23)(58:8)
they're (11:2)(32:10)(37:24)
thing (10:17)(39:1)(39:4)(39:5)(51:4)
things (10:10)(11:23)(14:24)(16:2)(16:10)(19:15)
(23:1)(23:4)(23:7)(23:13)(24:5)(29:2)(30:9)(38:14)
(39:12)(39:15)(48:17)(57:15)(58:2)
think (5:17)(12:1)(14:21)(15:8)(17:19)(19:14)(21:19)
(21:21)(25:8)(26:20)(28:6)(30:5)(30:16)(34:1)(34:11)
(38:22)(39:9)(40:2)(40:4)(41:17)(43:11)(43:18)(44:9)
(45:2)(46:1)(46:2)(46:18)(47:13)(47:14)(49:22)(62:5)
third (11:3)
this (4:5)(4:14)(4:18)(5:5)(6:18)(7:23)(8:8)(9:24)
(11:18)(12:1)(12:3)(12:7)(13:22)(14:18)(15:7)(15:21)
(19:1)(20:18)(20:19)(20:21)(21:24)(23:2)(23:9)(23:11)
(23:12)(23:16)(24:11)(24:15)(25:9)(26:1)(28:6)(28:19)
(29:16)(29:20)(30:6)(30:7)(30:8)(30:16)(32:16)(33:17)
(34:17)(35:5)(35:19)(36:10)(40:11)(40:17)(40:18)
(41:13)(42:5)(44:11)(45:4)(45:15)(46:3)(46:13)(47:23)
(49:13)(50:4)(51:4)(51:5)(52:2)(52:19)(53:18)(53:24)
(55:21)(56:1)(56:5)(57:12)(58:14)(58:18)(60:4)(63:10)
(63:12)(63:13)
those (4:7)(5:12)(5:18)(7:2)(8:8)(8:18)(12:9)(12:11)
(13:18)(15:18)(16:2)(16:10)(17:15)(17:18)(17:24)(18:3)
(20:16)(20:19)(21:11)(22:23)(23:4)(24:8)(24:23)(25:5)
(25:19)(25:23)(26:5)(27:6)(27:18)(29:21)(30:13)(34:18)
(34:24)(37:11)(37:12)(44:2)(48:14)(48:17)(55:13)(56:7)
(56:19)(57:7)(58:1)
though (6:8)
thought (23:2)(29:12)(45:14)
three (11:3)(11:5)(12:18)(13:1)(34:23)
through (10:7)(15:3)(26:22)
throughout (56:18)
tier (24:5)
time (4:5)(13:12)(17:11)(20:4)(27:12)(35:12)(39:19)
(39:22)(40:15)(49:12)(54:12)(57:14)(58:21)(59:16)
(60:13)(61:3)
timeline (17:22)(59:13)
timely (58:15)
times (30:13)
timing (53:18)
today (3:8)(3:23)(4:17)(8:13)(8:19)(8:21)(12:2)
(12:16)(19:20)(44:8)(44:14)(44:20)(45:16)(46:13)
(46:14)(48:21)(58:13)(58:24)(61:7)
together (56:24)
told (7:16)
too (47:6)
totally (21:20)
touch (4:10)
transcript (32:20)(44:11)(58:18)(63:5)
traveled (62:3)
trend (49:13)
trial (11:20)(11:22)(12:10)(12:14)(12:17)(14:17)
(17:17)(61:22)
tried (38:4)
true (31:17)(48:13)(63:5)
try (13:23)(29:3)(44:2)(46:19)(57:16)(58:1)
trying (23:18)(28:23)(34:8)(40:3)(40:4)(47:15)
turn (35:2)
two (5:18)(6:12)(8:18)(14:5)(26:14)(27:6)(35:6)
(38:14)(43:12)(45:18)(45:23)(51:12)(52:20)(53:2)(60:7)
two-tier (24:4)
tying (57:18)
type (11:17)(12:1)(38:4)(49:8)
types (16:2)(34:18)(39:3)(54:7)
typical (9:19)(14:21)(47:3)
typically (11:18)

U

ultimately (9:10)(17:17)
unable (11:4)(12:22)
uncommon (24:2)
under (17:12)(21:8)(23:3)(24:3)(26:10)(30:18)(30:19)
(36:2)(45:10)(58:11)
understand (30:4)(41:6)(41:11)
understanding (11:8)(11:24)(18:22)(29:20)
understood (8:7)
unexpected (43:9)
united (1:1)(1:14)(7:12)(7:22)(7:23)(17:8)(34:21)
(35:24)(36:3)(43:13)(43:15)(58:24)(59:1)
universally (21:5)(21:6)
unless (34:12)
unless you (14:6)
unlike (9:19)
unusual (16:3)
unworkable (35:7)
updates (25:1)
updating (25:3)
upon (35:10)
use (41:10)(46:10)(46:16)(54:20)(54:23)(56:8)(57:6)
(57:11)
used (9:11)(30:7)(46:24)(52:2)(55:11)
uses (47:5)
using (57:22)
usually (14:22)(30:14)(59:14)

V

validity (39:11)(50:2)(54:8)
variety (9:14)(13:10)
various (10:8)(54:3)
versata (45:16)(45:22)(46:7)(46:18)(46:19)(46:20)
(47:16)(48:22)(48:23)(49:7)(49:11)(50:12)(51:7)(52:11)
(54:14)(55:7)(55:12)(56:8)
version (9:18)(56:12)
versions (20:15)
very (8:3)(9:20)(16:15)(18:9)(20:9)(20:24)(27:3)
(28:20)(43:16)(46:17)(47:3)(62:4)
video (13:14)
view (8:24)(61:18)
viewing (57:15)
violation (22:5)
vis-à-vis (48:16)
voluntarily (7:12)(7:18)(7:23)(11:10)(11:13)(13:3)
(17:10)

W

wait (19:2)(33:20)(59:14)
want (5:6)(5:7)(12:3)(14:7)(19:9)(19:24)(23:23)(25:9)
(31:23)(34:2)(35:2)(39:3)(39:20)(39:22)(40:13)(46:4)
(46:19)(48:24)(49:23)(50:1)(50:23)(51:8)(60:1)(60:24)
(62:6)
wants (19:4)(40:6)(50:22)
was (4:5)(7:16)(10:17)(15:2)(18:18)(21:15)(26:9)
(26:17)(27:8)(29:12)(29:21)(30:2)(35:22)(39:2)(47:2)
(47:6)(48:2)(48:8)(48:23)(49:7)(49:8)(55:8)(55:12)

(56:14)(63:10)
wasn't (46:13)
wasting (17:11)
way (6:18)(11:17)(14:18)(19:14)(26:23)(30:6)(41:24)
(46:13)(47:23)(48:11)(48:19)(49:10)(50:2)(53:15)(56:9)
(57:12)(60:18)
ways (13:10)(13:15)
website (60:23)
week (15:7)(19:1)
weigh (43:6)
well (5:22)(6:16)(7:2)(8:3)(11:14)(12:7)(16:15)
(17:13)(18:8)(18:16)(20:9)(21:13)(21:18)(22:1)(27:11)
(30:22)(35:20)(38:18)(45:2)(59:5)(60:11)
were (6:6)(6:9)(15:5)(26:10)(29:3)(31:16)(34:7)(50:7)
(52:14)(56:5)(59:4)
we're (9:4)(17:6)(28:2)(28:12)(40:4)(47:15)(53:13)
weren't (30:18)
we've (11:4)(17:4)(37:17)(38:19)(60:7)
what (5:6)(8:21)(8:22)(12:21)(17:2)(17:4)(18:23)
(19:2)(22:7)(23:18)(24:10)(24:22)(25:7)(25:16)(25:23)
(25:24)(26:2)(26:20)(28:12)(28:23)(29:17)(30:5)(30:14)
(34:1)(34:5)(34:8)(36:19)(37:3)(37:8)(37:24)(39:7)
(40:3)(45:20)(46:2)(46:7)(46:8)(48:8)(48:18)(48:23)
(49:22)(49:23)(51:1)(53:13)(53:21)(58:23)(59:18)
what's (18:4)(28:18)
whatsoever (43:22)(47:18)
when (17:5)(17:6)(24:4)(24:21)(27:20)(30:7)(37:9)
(60:1)
where (11:7)(11:12)(16:4)(20:19)(20:21)(21:9)(21:12)
(24:5)(27:19)(29:9)(30:17)(33:8)(35:20)(36:21)(37:5)
(40:5)(45:7)(45:22)(46:4)(50:5)(56:14)(56:21)
whereas (9:23)
wherein (9:21)
whether (7:11)(7:12)(7:13)(7:20)(7:22)(8:14)(9:2)
(11:6)(13:11)(13:13)(13:24)(17:7)(21:10)(22:15)(25:4)
(28:8)(30:24)(31:1)(36:11)(40:20)(40:22)(45:9)(54:1)
which (4:16)(6:5)(9:11)(14:18)(14:20)(15:1)(17:1)
(26:20)(29:22)(30:12)(31:10)(33:10)(34:13)(35:4)(36:1)
(36:2)(38:19)(39:7)(41:3)(41:20)(44:5)(44:22)(46:6)
(54:2)(54:5)(54:18)(55:9)(63:10)
while (47:22)(57:17)
who (3:14)(3:15)(3:17)(4:8)(12:16)(17:16)(20:13)
(21:10)(21:23)(22:8)(22:21)(25:19)(27:14)(31:13)(45:9)
(55:11)
whole (9:13)(29:20)
wholesale (27:4)(28:24)
whom (25:18)
why (6:17)(19:11)(19:20)(22:8)(25:9)(29:2)(33:23)
(62:5)
will (4:16)(4:22)(5:23)(6:19)(7:1)(7:2)(7:12)(7:14)
(7:22)(8:1)(8:11)(8:18)(10:21)(10:23)(11:7)(11:9)
(12:1)(12:5)(12:16)(13:3)(13:7)(13:15)(13:24)(14:2)
(14:14)(15:7)(16:8)(16:10)(16:20)(17:5)(18:16)(18:24)
(19:18)(19:19)(20:7)(20:22)(25:3)(29:18)(29:23)(32:12)
(35:20)(37:4)(39:10)(42:4)(42:10)(42:12)(43:10)(43:19)
(44:2)(44:4)(44:10)(44:11)(44:12)(47:18)(47:21)(48:20)
(48:21)(50:2)(52:19)(53:9)(53:13)(53:22)(56:23)(56:24)
(57:13)(58:18)(58:19)(58:21)(59:11)(60:19)(62:1)
william (2:5)
willing (7:19)(8:9)(19:5)(34:4)(39:6)
wilmington (1:12)
wish (59:18)(59:19)
with (3:2)(3:8)(3:23)(4:2)(4:10)(4:11)(4:23)(5:3)
(5:13)(5:17)(6:14)(7:3)(8:20)(9:8)(10:8)(11:4)(11:23)
(12:6)(12:19)(12:21)(13:2)(13:20)(14:8)(14:11)(14:17)
(14:20)(15:13)(15:18)(16:16)(17:14)(17:23)(18:4)
(24:23)(24:24)(25:12)(25:17)(25:18)(26:12)(26:24)
(27:14)(28:1)(28:14)(28:19)(28:20)(28:21)(29:21)(30:3)
(30:16)(31:5)(31:12)(32:9)(32:23)(32:24)(35:6)(36:10)
(37:4)(37:10)(38:10)(39:2)(39:3)(39:10)(39:13)(39:14)
(39:19)(39:20)(39:23)(40:2)(40:5)(41:3)(41:21)(41:23)
(42:2)(44:3)(44:7)(44:10)(44:13)(44:21)(46:20)(48:4)
(48:9)(53:17)(55:18)(56:8)(57:2)(57:24)(58:8)(58:13)
(59:1)(59:2)(59:15)(60:22)(61:6)
without (11:16)(21:3)(23:16)(29:23)(57:8)
witness (11:19)(55:10)
witnesses (12:13)
wondering (35:23)
won't (11:9)(12:17)(53:14)
work (4:22)(7:24)(14:24)(18:2)(19:12)(19:13)(19:23)
(30:3)(34:19)(35:11)(35:21)(39:13)
working (10:7)(16:1)(16:9)
world (43:12)
worried (28:12)
would (7:17)(8:7)(9:4)(15:23)(16:3)(16:5)(17:22)
(18:1)(18:21)(19:13)(19:15)(21:14)(21:21)(23:2)(23:5)
(23:7)(23:9)(23:11)(25:21)(25:24)(26:3)(26:5)(26:11)
(26:12)(26:16)(26:19)(27:7)(27:24)(30:2)(31:17)(32:20)
(33:5)(34:10)(34:14)(39:6)(39:22)(41:20)(41:24)(44:14)
(48:14)(49:1)(49:10)(51:11)(54:5)(54:19)(56:3)(59:9)
wouldn't (8:8)(46:5)(48:18)
writing (15:6)(17:8)
written (32:11)(44:12)(53:16)(58:20)
wrong (6:3)

Y

year-and-a-half (12:11)
yes (53:3)
yet (13:22)
you (3:19)(4:7)(5:6)(5:7)(5:13)(5:23)(6:17)(8:6)
(11:19)(11:20)(12:5)(12:6)(12:9)(12:16)(12:18)(12:19)
(13:19)(14:7)(15:14)(17:14)(17:18)(17:22)(18:23)(19:1)
(19:2)(19:9)(19:12)(22:14)(23:6)(24:4)(24:14)(25:21)
(25:22)(26:12)(27:6)(27:23)(29:5)(29:8)(29:17)(30:11)
(30:20)(34:2)(34:3)(34:12)(38:5)(39:19)(39:22)(40:13)
(44:14)(45:1)(45:13)(46:14)(46:18)(46:19)(47:9)(48:6)
(53:22)(58:10)(58:13)(59:13)(60:1)(60:4)(61:2)(61:4)
(61:5)(61:12)(61:16)(61:19)(61:22)(61:23)(62:5)(62:7)
(62:8)(62:10)(62:11)
you'd (8:10)
your (3:5)(3:10)(3:21)(5:11)(5:20)(5:24)(7:6)(8:5)
(8:7)(16:19)(17:3)(17:21)(17:23)(18:6)(19:14)(20:6)
(21:13)(23:17)(24:18)(25:8)(26:6)(26:15)(26:20)(27:23)
(28:5)(29:9)(29:15)(29:19)(30:22)(31:23)(32:14)(32:20)
(34:2)(37:4)(38:7)(39:23)(40:12)(45:1)(49:11)(50:4)
(50:17)(51:8)(52:10)(52:16)(53:3)(60:4)(61:5)(61:8)
(61:11)(61:14)(61:17)(61:22)(62:10)(62:11)
you're (17:4)(17:15)(35:21)(39:22)(61:17)
you've (5:5)(62:3)

Z

zimmerman (2:5)(4:1)
zorvolex (9:10)(32:5)(32:10)(50:6)